UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel. MICHAEL DAUGHERTY, Plaintiff,

Case No. 1:08-cv-354

Spiegel, J. Litkovitz, M.J.

v.

BOSTWICK LABBORATORIES, et al., Defendants.

ORDER

Plaintiff Michael Daugherty (relator) brings this *qui tam* action alleging that defendants

Bostwick Laboratories and David Bostwick, M.D., violated the Anti-Kickback Statute, 42 U.S.C.

§ 1320a-7b(b), the Stark Laws, 42 U.S.C. § 1395nn, and the False Claims Act, 31 U.S.C. §§

3729-3733 by: (1) submitting false claims to Medicare, Medicaid, and other federally-funded programs for non-allowable lab services done without a physician's order; and (2) billing federally-funded healthcare programs for lab services unlawfully referred to defendants. (Doc. 34). This matter is before the Court on the parties' dispute over the appropriateness of an "Attorneys' Eyes Only" provision in the proposed protective order. 1-2

I. Background

Relator is the president of LabMD, an Atlanta-based urology and uropathology laboratory. (Doc. 34). Defendant David Bostwick is the founder of defendant Bostwick Laboratories, which provides laboratory and pathology services. The bulk of Bostwick Laboratories' revenue comes from its urology business. *Id.* Relator filed this action in May 2008 on behalf of the United States of America (Government). (Doc. 1). In June 2011, the Government filed its Notice of Election to Decline Intervention. (Doc. 18). The District Judge

¹All other terms of the proposed protective order have been agreed upon by the parties.

²Pursuant to § I.D. of the undersigned's Pretrial Procedures, the parties have submitted letters setting forth their positions on the instant discovery dispute. Those letters are attached to this Order, with the exception of the exhibits attached to relator's affidavit.

subsequently entered an Order unsealing the complaint and permitting relator to serve defendants. (Doc. 19). Relator filed an amended complaint in February 2012. (Doc. 34). Defendants filed separate motions to dismiss (Docs. 39, 56) and a joint motion to change venue (Doc. 82); these motions were denied. (Docs. 70, 92). The litigation is currently in the beginning stages of discovery.

Relator and defendants agree that a protective order is appropriate in this matter as the documents to be exchanged in discovery will include, among other things, confidential medical records of non-party individuals and defendants' pricing agreements with non-party entities. The parties dispute, however, whether the proposed protective order should include an "Attorneys' Eyes Only" (AEO) designation for specific categories of documents. Defendants assert that an AEO designation is appropriate for discrete categories of documents as relator and defendants are direct competitors in the laboratory services industry and permitting relator access to defendants' pricing schedules and other proprietary information will competitively harm defendants. In contrast, relator contends that an AEO designation is unnecessary as: (1) the parties are not direct competitors; (2) a standard protective order will sufficiently protect defendants' interests; and (3) relator would not be able to use defendants' pricing and proprietary information because, according to his allegations, their practices are illegal. Relator further claims that including an AEO designation would hinder the prosecution of this matter as relator's counsel intends to rely on relator's experience and expertise in the laboratory services industry to analyze defendants' pricing schedules to prove relator's claims.

The undersigned Magistrate Judge has conferred with the parties on several occasions in order to narrow the scope of this dispute. At the Court's request, the parties have submitted several informal briefings outlining their respective positions, as well as a sampling of

documents for *in camera review* that defendants assert should be AEO designated. Most recently, the parties submitted letter briefs supported by affidavits and other evidence. The issue of the scope of the proposed protective order is now ripe for resolution.

II. Standard of Law

Federal Rule of Civil Procedure 26 provides that "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Fed. R. Civ. P. 26(c). The entry of a protective order rests with the sound discretion of the Court. *Procter & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219, 227 (6th Cir. 1996). Nevertheless, the Court is mindful that its discretion to issue protective orders is "limited by the careful dictates of [Rule] 26 and 'is circumscribed by a long-established legal tradition' which values public access to court proceedings." *Id.* (citing *Brown & Williamson Tobacco Corp. v. Fed. Trad Comm'n.*, 710 F.2d 1165, 1177 (6th Cir. 1983)).

"In general, courts utilize 'attorneys' eyes only' protective orders when especially sensitive information is at issue or the information is to be provided to a competitor."

Westbrook v. Charlie Sciara & Son Produce Co., Inc., No. 07-2657, 2008 WL 839745, at *4

(W.D. Tenn. Mar. 27, 2008) (citing cases). See also Arvoc Container Corp. v. Weyerhaeuser

Co., No. 1:08-CV-548, 2009 WL 311125, at *5 (W.D. Mich. Feb. 9, 2009) ("To be sure, courts in many circumstances have found that a specific showing of competitive harm justifies a restriction of confidential or trade secret information to 'attorney's eyes only."). The party moving for the restrictive AEO designation must detail the alleged harm it is likely to suffer absent the requested protection "with a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements." Nemir v. Mitsubishi Motors, Corp., 381 F.3d 540, 550 (6th Cir. 2004) (quoting Gulf Oil Co. v. Bernard, 452 U.S. 89, 102 n.16

(1981)). In determining whether good cause exists for an AEO designation, courts must balance "the difficulties imposed upon plaintiff against the need to protect information from abuse by competitors." *Arveo Container*, 2009 WL 311125, at *6.

III. Discussion

Defendants assert that AEO designation is appropriate for discrete types of discoverable documents to protect sensitive competitive information. Defendants seek to designate the following categories of documents as AEO documents: (1) trade secrets; (2) sensitive confidential business or financial information, including pricing offered to actual or prospective customers or pricing obtained from suppliers and partners; (3) competitive technical information, including technical analyses or comparisons of competitor's products or services; (4) competitive business information, including marketing analyses or comparisons of competitors' products or services and strategic planning; and (5) confidential health information.³

At the Court's request, defendants submitted a representative sampling of documents for *in camera* review. These documents were shared with relator's counsel and, subsequently, an informal discovery conference was held on May 22, 2013. During this conference, the undersigned determined that documents falling under the umbrella of category (5) above, regarding confidential health information, *i.e.*, patient records which are protected under HIPPA,⁴ would be sufficiently protected by a protective order and would not be subject to an AEO designation.⁵ Consequently, the instant determination is limited to categories (1) through (4) as

³These categories reflect those identified by defendants in their proposed protective order submitted in conjunction with their May 8, 2013 letter brief to the Court. The documents submitted for *in camera* review, per defendants' May 20, 2013 letter brief, are categorized as follows: (1) pricing to customers; (2) pricing from suppliers; (3) market analyses; (4) revenue analysis; and (5) laboratory policies and procedures. For clarity's sake, the Court will incorporate these latter categories into those initially identified by defendants in their proposed protective order.

⁴The Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d, et seq.

⁵HIPAA permits disclosure of protected health information "in the course of any judicial or administrative proceeding" where a qualified protective order exists ensuring that the parties will not disclosure the information for

identified by defendants.

A. Category 1: Trade Secrets⁶

Defendants submitted only one document exemplar (Exhibit 15) of trade secrets they contend should be AEO designated: a copy of Bostwick Laboratories' standard operating procedure (SOP) for UroVysion FISH (fluorescence in situ hybridization) testing equipment.⁷ Defendants assert that relator could use this and similar SOPs to enhance his own laboratory processes. Defendants appear to assert that the SOP includes proprietary information regarding specific methods designed and employed by Bostwick Laboratories in using FISH testing equipment. Relator disputes this assertion and claims that the manufacturer of the FISH testing equipment sets the SOPs and it is unclear how defendants' procedures are proprietary as there is no evidence that they substantially deviate from the manufacturer's. Relator therefore contends that defendants have failed to demonstrate that permitting relator to review the submitted SOP (and others documents in this category) is likely to cause competitive harm. The undersigned agrees.

Defendants have not made the "particular and specific demonstration of fact" necessary to justify applying the highly restrictive AEO designation to its SOPs. *Nemir*, 381 F.3d at 550. *See also Arvco Container*, 2009 WL 311125, at *7 (party seeking AEO designation for purported trade secrets must prove that material is proprietary). While defendants have made factual showings that they are likely to suffer competitive harm should relator be privy to certain pricing agreements, as discussed further *infra*, they have not put forth any factual support from which the Court can discern defendants will suffer harm outweighing the likely prejudice to relator

any purpose other than the pending litigation and that the information will be returned or destroyed at the conclusion of the litigation. 45 C.F.R. § 164.512(e)(1).

⁶Category 1 encompasses the "laboratory policies and procedures" category identified in defendants' May 20, 2013 letter brief.

⁷ This document bears the Bates Label DBL000000596.

should the SOPs not be afforded the second-tier AEO protection. The Court is also sensitive to the fact "that the indiscriminate use of [AEO] protective orders does pose a significant handicap on the restricted litigant." *Arvco Container*, 2009 WL 311125, at *6. In the absence of a factual showing that defendants will suffer competitive harm unless the SOPs are AEO designated, the undersigned finds that defendants' interests are adequately protected by the general terms of the proposed protective order. Thus, the documents in Category 1: Trade Secrets do not qualify for AEO designation.

B. Category 2: Confidential Business or Financial Information⁸

Of the fifteen exhibits submitted by defendants, eleven fall within Category 2 relating to "Confidential Business or Financial Information." These documents are as follows:

- Exhibit 1 (0.7.215.20293): TC-Split Revenue Assessment;
- Exhibit 2 (DBL 000000003): a contract between Bostwick Laboratories and a customer which includes specific pricing agreements;
- Exhibit 3 (DBL 000000009): a direct bill proposal from Bostwick Laboratories to a prospective customer;
- Exhibit 4 (DBL000006600): a proposal from Bostwick Laboratories to a client including pricing agreements;
- Exhibit 5 (DBL000004539): a direct bill agreement between Bostwick Laboratories and an existing client;
- Exhibit 6 (DBL000008543) and Exhibit 7 (DBL000018099): internal emails regarding negotiated prices for laboratory procedures for existing Bostwick Laboratories' clients;
- Exhibit 8 (DBL000038652; DBL000038652_0001-05): an internal email including an attached contract for services between Bostwick Laboratories and an existing customer which includes prices offered;
- Exhibit 9 (DBL000030823): an internal email regarding Bostwick Laboratories' pricing for various laboratory tests negotiated with a prospective customer;

⁸Category 2 correlates to documents falling within the "pricing to customers" and "pricing from suppliers" categories identified in defendants' May 20, 2013 letter brief.

- Exhibit 10 (DBL000041141): a spreadsheet documenting commissions earned by a Bostwick Laboratories' sales representative which includes tests ordered by customers and prices offered; and
- Exhibit 11 (DBL000006078): a business strategy analysis prepared by defendant David Bostwick including prices Bostwick Laboratories negotiated with equipment suppliers.

Defendants assert these documents are entitled to AEO designation as they contain sensitive pricing information and agreements between Bostwick Laboratories and customers and suppliers which, if known to relator, could cause defendants competitive harm. Defendants support these assertions with affidavits from Gerard E. Diffley, the Chief Compliance Officer of Bostwick Laboratories, and Kevin C. Johnson, an individual with over 30 years of experience in the medical diagnostic laboratory industry including previously holding the position of Chief Executive Officer of a laboratory testing services provider and who currently serves on the board of directors for three laboratory and life science companies.

Mr. Diffley states that the clinical laboratory industry is highly competitive and that price is one of the most important factors in winning new and maintaining old business. Mr. Diffley further states that the prices offered are the result of Bostwick Laboratories' negotiations with current and prospective clients and that this information is not publicly available. According to Mr. Diffley, a small price difference in a specific test, such as offering \$1.00 less per test, could have a large impact as clients order thousands of tests annually; consequently, were relator aware of Bostwick Laboratories' prices he could offer discounts to its customers which would result in a loss of business to defendants. Attached to Mr. Diffley's affidavit is a screen shot of relator's website which provides that relator's company, LabMD, has a national client base. *See* http://michaeljdaugherty.com/about/ (last visited June 21, 2013). Mr. Diffley states that if relator has knowledge of defendants' pricing agreements with its customers and suppliers, he could

severely impair defendants' ability to compete on a national level by offering minimal discounts which defendants could not match.

Mr. Johnson states that he has no prior or current business relationship with either defendants or relator and that he offers his testimony without any remuneration. Mr. Johnson declares that, in his experience, pricing is one of the most important factors among competitive laboratories; therefore, laboratories consider the specific prices they offer to physicians, health plans, and other non-government entities to be confidential and do not disclose this information to competitors. Mr. Johnson further states that if a laboratory had knowledge of a competitor's pricing it would gain a competitive advantage as it could offer slightly lower prices to induce a competitor's clients to switch laboratories. Mr. Johnson states that because of this potential for competitive advantage and harm through loss of business, during his twenty plus years of employment with clinical laboratory companies, such pricing agreements were not available to the general public or competitors.

In contrast, relator contends that because pricing is heavily regulated under the Anti-Kickback Statute, that the laboratory services industry is not a price-competitive market. Relator has submitted his own affidavit in which he attests that the identities of and prices paid by laboratory clients are not confidential and that this information is routinely shared with competitor laboratories by physicians seeking discount pricing. To illustrate this point, relator attaches three exhibits to his affidavit which are Bostwick Laboratories' pricing proposals provided to relator by physicians seeking lower prices. Relator contends that granting defendants' request to designate such documents AEO protected would lead to the odd outcome of relator having access to this information from non-parties while being precluded from reviewing the same documents when produced by defendants. Relator further asserts that the

identity and prices offered by suppliers should not be subject to AEO designation as defendants and relator are not in the same competitive market. Relator states that LabMD is a regional laboratory with only one sales representative and 20 accounts in the southeast territory whereas Bostwick Laboratories is much larger; consequently, relator is not in the financial position to negotiate pricing with private payors.

The Court finds that defendants have demonstrated good cause supported by specific showings of fact for applying an AEO designation to the Category 2 documents.

First, defendants have proffered the affidavit of Mr. Johnson, a non-party with extensive experience in the clinical laboratory services industry. While the affidavits of Mr. Diffley, a Bostwick Laboratories' employee, and relator are informative, they are both interested parties. Mr. Johnson's affidavit, on the other hand, provides a more neutral and overarching perspective as to the competitive nature of the laboratory services industry where price is a key factor in how laboratories obtain and maintain clients and suppliers. This evidence demonstrates that defendants could suffer economic harm should relator, its direct competitor, be permitted access to its pricing arrangements. Such a showing justifies imposing an AEO restriction on the financial information contained in these documents.

Second, the undersigned is not persuaded by relator's argument that the existence of the Anti-Kickback Statute prevents significant market competition in the laboratory services industry. Indeed, the Court's research indicates that the Anti-Kickback Statute includes a discount safe harbor which is "intended to *encourage price competition* that benefits the Medicare and Medicaid programs." 56 Fed. Reg. at 35953 (emphasis added). Certain discounting practices were explicitly excluded from criminal liability under the Anti-Kickback Statute to "encourage providers to seek discounts as a good business practice which results in

savings" to these programs. H.R.Rep. 95-393, at 53 (1977). "The [discount] exception, then, reflects a predictive understanding that competitive pricing schemes within the health care field will lower the cost of health care services and goods." *United States v. Shaw*, 106 F. Supp.2d 103, 115 (D. Mass. 2000). It thus appears that Congress not only anticipated, but encouraged competitive pricing in the health services industry. Consequently, the undersigned does not agree with relator's contention that the laboratory services industry is not competitive.

Third, the attachments to relator's affidavit demonstrate that the parties' industry is highly competitive when it comes to pricing. Relator states that physicians regularly disclose the prices they pay to laboratories in order to solicit discounts as demonstrated by the proffered attachments – pricing proposals from Bostwick Laboratories to physicians and physician practices. Notably, relator does not state that his *competitors* regularly share their pricing information and, further, the attached exhibits are merely proposals and not pricing agreements. As relator himself has demonstrated, the parties' industry is highly competitive in regards to laboratory servicing prices.

Fourth, while relator maintains that his business is small and incapable of competing with Bostwick Laboratories, the evidence submitted by defendants demonstrate that relator holds himself out as a national provider of laboratory services. Thus, while relator may not currently provide laboratory services on a national level, this evidence suggests that he is capable of doing so.

In light of the above, the Court finds that documents falling within Category 2 are properly subject to AEO protection as defendants have made "a specific showing of competitive harm" that is likely should its confidential pricing information be shared with relator, a direct competitor in the laboratory services industry. *See Westbrook*, 2008 WL 839745, at *4; *Arvco*

Container, 2009 WL 311125, at *5. However, the undersigned finds that the evidence proffered by defendants only supports a finding that *current* pricing information is subject to AEO designation as there is no evidence that defendants' historic pricing agreements could be used by relator to cause defendants economic harm. The more dated the pricing information, the less likely it could be used to cause defendants competitive harm. As the parties have not provided the Court with a methodology for distinguishing what information is currently commercially useful from that which is not, the Court determines that applying the AEO designation to information going back two years from the date of this Order reasonably protects defendants' competitive interests. Therefore, the AEO designation will apply only to current pricing agreements and proposals, which the Court defines as information dated after July 1, 2011.

Lastly, the undersigned notes that defendants have identified that for Exhibits 2, 9, and 11, which contain non-financial information such as general contract terms and cover emails, they seek only to designate those portions containing pricing information as AEO protected. The Court agrees that only those portions of these documents containing pricing information are subject to AEO designation. Accordingly, in all future document productions, defendants shall likewise clearly identify the non-AEO protected portions of produced documents.

C. Category 3: Competitive Technical Information

Upon review of the documents submitted by defendants for *in camera* review, none appear to fall within this category which defendants describe in their proposed protective order as consisting of documents such as technical analyses or comparisons of competitor's products or services. Without any documents to review, the undersigned is unable to conclude that documents falling within this category should be AEO designated. To the extent this category may include documents addressed above or below in connection with Categories 2 or 4, they will

receive AEO designation consistent with those rulings.

D. Category 4: Competitive Business Information

Defendants have submitted three documents which they claim exemplify Category 4 documents containing competitive business information, such as documents revealing market strategy and other non-public information, which should receive AEO designation under the protective order: (1) Exhibit 12 (DBL000017301) – containing business metrics of defendants' urology practice; (2) Exhibit 13 (DBL000013362) – meeting minutes which include business metrics such as lost business; and (3) Exhibit 14 (DBL000029133) – communication from defendants' billing partner detailing defendants' business metrics and cash flow and projections. Defendants assert that these documents concern the current status of their business and contain details, such as certain at-risk client relationships, and that this information could be easily utilized by a direct competitor like relator to win clients, thereby causing defendants economic harm.

Relator asserts that defendants will not suffer economic harm should this information be available to relator as he is alleging that defendants' marketing schemes are illegal. Further, relator asserts that only information that could potentially be competitively sensitive is that involving business in the southeast region where relator does business.

A review of these documents clearly demonstrates that the financial information contained therein could be used to economically harm defendants. The exhibits provided include names of clients, the types and volumes of tests ordered, and the revenue garnered therefrom, and defendants' areas of sales weakness. An AEO designation for this information is appropriate as relator is a direct competitor with defendants. *See Westbrook*, 2008 WL 839745, at *4 (citing cases). Further, as stated above, relator holds his corporation, LabMD, out as a national provider

of laboratory testing services. Therefore, his contention that only information regarding southeastern business is potentially competitively sensitive is not persuasive.

The undersigned thus finds that it is appropriate to designate the financial and competitive business information falling within Category 4 as AEO protected. Again, the AEO designation will apply only to current documents defined as information dated after July 1, 2011.

IV. Conclusion

For the above stated reasons, the undersigned finds that an AEO designation is appropriate for the following categories of documents: Category 2: Confidential Business or Financial Information and Category 4: Competitive Business Information. However, defendants have failed to demonstrate that at AEO designation is appropriate for documents falling within Category 1: Trade Secrets; therefore, documents in this category shall be produced subject only to the general provisions of the proposed protective order. Similarly, defendants did not submit any documents falling squarely within Category 3: Competitive Technical Information and the undersigned finds no basis for affording AEO protection to documents in this category. The parties shall submit a proposed protective order consistent with this order reflecting their agreements and the terms of this order within fourteen days.

IT IS SO ORDERED.

Date: 6/24/13

Karen L. Litkovitz

United States Magistrate Judge

MINTZ LEVIN

Matthew D. Levitt | 617 348 1646 | MDLevitt@Mintz.com

One Financial Center Boston, MA 02111 617-542-6000 617-542-2241 fax www.mintz.com

May 8, 2013

VIA EMAIL

Hon. Karen Litkovitz United States Magistrate Judge Potter Stewart U.S. Courthouse 100 East Fifth Street Cincinnati, OH 45202

Re: U.S. ex rel. Daugherty v. Bostwick Laboratories, et al,

Civ. No. 1:08-cv-00354-SAS-KLL

Magistrate Judge Litkovitz:

In accordance with your Honor's instructions during the May 2, 2013 teleconference with the Parties, ^{1/} we submit this letter brief on behalf of Defendant Bostwick Laboratories ("Bostwick") to set forth why a two-tiered protective order providing for an Attorneys' Eyes Only designation is appropriate and necessary in this case. We also submit, as Exhibit A to this letter, a copy of Bostwick's proposed protective order, which, as discussed during the May 2nd teleconference, differs from the order proposed by Relator only with respect to the inclusion of an Attorneys' Eyes Only designation.

An Attorneys' Eyes Only designation is necessary for certain documents revealing Bostwick's sensitive competitive information because Relator, the president of a urology and uropathology laboratory, is, admittedly, one of Bostwick's direct competitors. Indeed, Relator has alleged that "[i]n the course of his business, Relator provides similar laboratory services to physician customers, some of which have been or currently are also customers of Bostwick Laboratories." As the president of a competing laboratory, Relator cannot deny that he is involved in the competitive decision making of his company.

Throughout this letter, reference is made to Relator, Michael Daugherty, and Defendants Bostwick Laboratories and Dr. David Bostwick, collectively as "the Parties."

Amended Complaint, ¶ 20.

The fact that Relator may not compete with Bostwick in every state does not make the threat of competitive harm to Bostwick any less real or the need to adequately protect against that harm any less compelling. To the

May 8, 2013 Hon. Karen Litkovitz Page 2 of 7

Bostwick has spent the past fourteen years building and maintaining its competitive edge in the industry. If Relator is permitted direct access to Bostwick's sensitive competitive information, he will gain an unfair business advantage while at the same time threatening and possibly irreparably damaging Bostwick. It is not difficult to imagine the harm that Bostwick would suffer if its direct competitor, Relator, were to gain information regarding, for example, (i) the pricing and terms offered by Bostwick to specific customers; (ii) the pricing and terms that Bostwick has obtained from its suppliers, distributors or other business partners; (iii) trade secrets, including laboratory operating procedures; and (iv) complex and detailed internal analyses of market conditions and competing technology and services.

This harm to Bostwick would be significant and largely irreparable, and it is altogether avoidable with an order limiting disclosure of the types of sensitive competitive information set forth below to Relator's counsel and experts retained in this matter. Such an order would serve to protect Bostwick's hard-earned competitive position in the industry without impeding Relator's ability to prepare for trial.

Overview of Bostwick's Proposed Protective Order

Bostwick has proposed two tiers of protected materials to protect the Parties' confidential and proprietary information subject to discovery in this case. Under Bostwick's proposed order, a party producing materials in connection with this litigation may designate certain types of information as either "Confidential" or "Confidential – Attorneys' Eyes Only." Materials produced under the latter designation may only be disclosed to the Parties' counsel and retained experts.

Because the Parties are in the early stages of collecting documents requested by the other in discovery, Bostwick cannot enumerate the entirety of specific documents to be produced that would warrant application of an Attorneys' Eyes Only designation. Nor would an individual document-by-document evaluation even be feasible in this case, given that Relator's broad discovery requests potentially include documents from dozens of custodians going back a

May 8, 2013 Hon. Karen Litkovitz Page 3 of 7

decade. At this juncture, Bostwick would seek to designate as Attorneys' Eyes Only a subset of its confidential proprietary business information, including: (i) competitive business information, such as non-public financial or marketing analyses, or analyses of competitors' products or services and strategic planning; (ii) confidential business or financial information and records, such as strategic business planning or sensitive marketing information, the identity of Bostwick's suppliers, distributors, and potential or current customers, and payer contracts or other documents disclosing terms, pricing, or strategic business alliances; (iii) trade secrets; (iv) competitive technical information, including technical analyses of competitor's products or services; and (v) confidential health information.^{4/}

The voluminous discovery anticipated to be produced in this case makes it impractical for the Court to identify documents as Attorneys' Eyes Only on a case-by-case basis. Accordingly, Bostwick has proposed a reasonable procedure permitting the Parties to designate documents as Attorneys Eyes' Only as they review and produce documents in the ordinary course of discovery only if they fall into the defined categories above. ^{5/} Under Bostwick's proposed protective order, each of the Parties has a good faith obligation to limit their designation of Attorneys' Eyes Only documents to those documents meriting such additional protection. In fact, recognizing that disputes about the categorization of individual documents may arise, Bostwick's proposed order includes a procedure by which any party can dispute a confidentiality designation assigned by another party. Thus, if Relator's counsel believes that Bostwick is "over-designating" information as Attorneys' Eyes Only, the Parties will be obliged to confer, and the objecting party may seek relief from the Court if the parties are unable to resolve the dispute. Consistent with applicable law, a party designating information as Attorneys' Eyes Only ultimately bears the

From the outset of this litigation, Bostwick has proposed a two-tiered protective order to include an Attorneys' Eyes Only Designation. If a two-tiered order is entered by the Court, Bostwick believes that the confidential health information of its patients warrants the highest level of protection and, therefore, should be treated as Attorneys' Eyes Only.

Anticipating that discovery may reveal categories of documents that cannot be foreseen but that merit heightened protection, Bostwick's proposed order also permits the designation as Attorneys' Eyes Only of documents which, if disclosed, are reasonably likely to cause harm to the producing party. As with all documents subject to the protective order, the Parties are obliged to act in good faith when designating documents as Attorneys' Eyes Only pursuant to this provision.

May 8, 2013 Hon. Karen Litkovitz Page 4 of 7

burden of justifying that designation to the Court, limiting any incentive by the Parties to "over-designate" materials as "Attorneys' Eyes Only."

The Federal Rules and Case Law Recognize the Need To Limit Disclosure of Certain Information to Counsel Where the Parties Are Competitors In the Same Industry

The Federal Rules of Civil Procedure permit a district court to adopt procedural safeguards to protect confidential commercial information. See Michel v. WM Healthcare Solutions, Inc., 2011 U.S. Dist. LEXIS 142747, at *10-11 (S.D. Ohio Sept. 8, 2011) (Litkovitz, J.), quoting R.C. Olmstead, Inc., v. CU Interface, LLC, 606 F.3d 262, 269 (6th Cir. 2010) ("Federal Rule of Civil Procedure 26(c)(1)(G) permits a district court to require that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only a specified way."). In cases where, as here, a party seeking discovery is a direct competitor of the producing party, this Court has recognized that it is appropriate to "limit access to...[certain confidential] information to counsel, and counsel's associates and employees (and thereby preclude disclosure to any of Defendants' competitors, including Plaintiffs)." Liberty Folder v. Curtiss Anthony Corp., 90 F.R.D. 80, 82-83 (S.D. Ohio 1981); see Safety Today, Inc. v. Rov. No. 212-cy-510, 212-cy-929, 2013 U.S. Dist, LEXIS 43659, at *13-15 (S.D. Ohio March 27, 2013) (Kemp, J.) (where the parties were "business competitors" and disclosure of defendant's sensitive business information to plaintiff could "affect [the defendant's] competitive position in the marketplace," an attorneys' eyes only designation was a "practical and costeffective way" to protect defendant's interests); Crane Plastics Co. v. Louisiana-Pacific Corp., 119 F. Supp. 2d 749, 752 (S.D. Ohio 2000) (recognizing that limiting discovery of confidential trade secrets to outside counsel "ordinarily addresses most of the concerns about the production of such information to a competitor"); 3 Sigma Corp. v. NuCoat, Inc., No. 3:10-cv-085, 2011 U.S. Dist. LEXIS 102697, at *3 (S.D. Ohio Sept. 12, 2011) (denying motion to modify protective order to permit plaintiff's expert to view documents designated as attorneys' eyes only where expert was in the business of consulting in the industry and plaintiff failed to show that "such disclosure will not, in itself, work a competitive harm to Defendants").

Courts have routinely recognized that when parties compete in the same industry, an Attorneys' Eyes Only designation strikes the appropriate balance between a litigant's right to

May 8, 2013 Hon. Karen Litkovitz Page 5 of 7

relevant discoverable information and the legitimate concerns surrounding disclosure of highly confidential and sensitive information to a direct competitor. See, e.g., Association Voice, Inc. v. AtHomeNet, Inc., No. 10-cv-00109, 2010 U.S. Dist. LEXIS 38476, at *8-9 (D. Col. Mar. 29, 2010) (adopting, over plaintiff's objection, defendant's two-tier protective order where defendant argued that "disclosure of certain information without an 'attorney's eyes only' protective designation would give Plaintiff, a competitor, a distinct competitive advantage"); UCC Ueshima Coffee Co., Ltd. v. Tully's Coffee Corp., No. C06-1604RSL, 2007 U.S. Dist. LEXIS 98157, at *4-5 (W.D. Wash. Mar. 6, 2007) (limiting disclosure of plaintiff's list of business contacts only to defendant's attorneys and experts where plaintiff argued that disclosure directly to defendant, a direct competitor, would harm plaintiff "[r]egardless of whether defendant actively uses the information"); Fieldturf Int'l, Inc. v. Triexe Mgmt. Group, Inc., No. 03-C-3512, 2004 U.S. Dist. LEXIS 6676, at *9-10 (N.D. III. April 16, 2004) (defendant's financial information was discoverable on an outside counsel "attorneys' eyes only" basis where disclosing such information to plaintiff, a direct competitor, could cause the defendant "great harm"); Asch/Grossbardt Inc. v. Asher Jewelry Co., No. 02-Civ-5914, 2003 U.S. Dist. LEXIS 2837, at *7-8 (S.D.N.Y. Feb. 28, 2003) (recognizing that "where the parties are direct competitors, as here, disclosure of customer lists could potentially result in economic harm to the disclosing party" and limiting discovery of plaintiff's customer list to defendants' attorneys).

Courts Have Recognized that an Attorneys' Eyes Only Designation is Appropriate in *Qui Tam* Actions Where the Parties Are Competitors

The nature of Relator's allegations does not alter the well-established principles discussed above. In any case, including *qui tam* actions, it is the nature of the parties' relationship and the nature of the information subject to discovery that will necessitate the procedural safeguards that only an Attorney's Eyes Only designation can provide. ⁶/ Relying on cases like *United States ex*

As we discussed in the May 2, 2013 teleconference with your Honor, the Parties have met and conferred on the appropriateness of an Attorneys' Eyes Only designation numerous times over the past few months. As a part of that process, the Parties set forth and exchanged their respective positions on this issue, with the intention of submitting a joint motion to the Court. In his proposed submission, Relator had suggested that Bostwick's fear of damage to its competitive position in the industry is unfounded because of the nature of Relator's allegations. Indeed, Relator has taken the position that no competitor, including Relator, could ever utilize the sensitive information it learns about Bostwick's business practices without violating federal law. Of course, the fact that Relator has alleged that certain of Bostwick's business practices are unlawful does not make them so. Bostwick's

May 8, 2013 Hon. Karen Litkovitz Page 6 of 7

rel. Meyer v. Kempf Surgical Appliances, Inc., No. 1:11-CV-0111 (S.D. Ohio, filed Feb. 25, 2011) and United States ex rel. McDonough v. Symphony Diagnostic Services, Inc., et al., No. 2:08-cv-00114 (S.D. Ohio, filed Feb. 7, 2008), Relator has taken the position that an Attorneys' Eyes Only designation is not necessary in a qui tam action like this one. But both Meyer and McDonough are distinguishable from this case for at least two reasons.

First, there is no evidence that the defendant in either of those cases ever sought the protection of an Attorneys' Eyes Only designation, like Bostwick seeks here. To the contrary, in both *Meyer* and *McDonough*, the defendant consented to a one-tier protective order, which the Court then adopted. Those cases, therefore, cannot offer any insight on the issues presented here because the Court was not asked to issue, and did not issue, an opinion as to whether an Attorneys' Eyes Only designation was appropriate in those cases.

Second, unlike the Parties here, the parties in *Meyer* and *McDonough* were not direct competitors in the same industry. Instead, the relators were former employees of the defendant-corporations. The relationship between the parties simply did not present the threat in this case that disclosure of sensitive competitive business information to the relator could result in calamitous competitive harm to the defendant.

Thus, while an Attorneys' Eyes Only designation may not be necessary in every *qui tam* action where sensitive and competitive information is subject to discovery, it is certainly justifiable here, where the Parties are direct competitors in the very same industry. *See, e.g., U.S. ex. rel. Health Dimensions Rehabilitation, Inc. v. Rehabcare Group, Inc.*, No. 4:12-CV-00848, 2012 U.S. Dist. LEXIS 169493, at *4, 6 (E.D. Mo. Nov. 29, 2012) (holding, in a case where relator and defendants were direct competitors, that access to documents that could cause the defendant "competitive long term harm" if disclosed to its competitors, should be limited to the government and relator's counsel).

May 8, 2013 Hon. Karen Litkovitz Page 7 of 7

The Balance of Harms Weighs in Favor of Protecting Bostwick's Sensitive Competitive Information Through an Attorneys' Eyes Only Designation

To date, Relator has not articulated any reason why he would need direct access to Bostwick's sensitive competitive information in order to prepare for trial. Relator has also not identified any harm that will result if he is not permitted direct access to such information. Nor can he: under Bostwick's proposed order, Relator's counsel and experts will have unfettered access to documents designated as Attorneys' Eyes Only. Relator's ability to prepare for trial in this case, therefore, will not be encumbered. See R.C. Olmstead, Inc. v. CU Interface LLC, 606 F.3d 262, 265, 269 (6th Cir. 2010) (district court's order limiting discovery of defendant's trade secrets to counsel and experts where the parties were direct competitors did not, as plaintiff contended, "unfairly inhibit[]" plaintiff's ability to prove its claims).

Even if Relator could articulate some type of harm, that harm is greatly outweighed by the serious damage that Bostwick will suffer if it is forced to disclose its sensitive competitive information directly to its competitor. The appropriate way to shield Bostwick from such harm is through the entry of a protective order containing an Attorneys' Eyes Only provision.

Respectfully submitted,

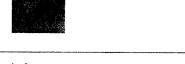
matter of Livet

Matthew D. Levitt

cc: W.J. Sefton, Esq.
Hope S. Foster, Esq.
Michael S. Gardener, Esq.
Stefanie G. Abhar, Esq.

Christopher Muzzo, Esq. Stephen Miller, Esq. Calli Jo Varner, Esq.

Jennifer Verkamp, Esq. Frederick Morgan, Esq. James Keller, Esq.



MORGANVERKAMPLLC

By Electronic Mail

May 8, 2013

Hon. Karen Litkovitz
United States District Court Judge
for the Southern District of Ohio

Re: Letter Brief, U.S. ex rel. Daugherty v. Bostwick Laboratories, et al.,

Case No. 1:08-cv-354

Dear Magistrate Litkovitz:

This letter addresses the dispute between Relator and Defendants regarding the appropriateness of an "Attorney Eyes Only" provision in the proposed protective order. All other terms have been agreed upon.

Relator Mike Daugherty brings allegations under the federal False Claims Act and various state False Claims Acts that Defendants engaged in a nationwide scheme to cause the submission of false claims for payments to government healthcare programs by (1) improperly billing for unordered tests; and (2) by offering and paying kickbacks to physicians in exchange for the referral of laboratory services.¹

For the reasons set forth below, Relator does not agree that an "Attorneys' Eyes Only" designation in warranted in this case. Relator strongly objects to a restriction that prevents counsel from sharing discovery documents with their client, particularly when all such documents can be properly protected by designation under the existing provisions of the protective order.

¹ By way of brief procedural background: The case was briefly stayed until the Court ruled on Motions to Dismiss, which were pending until the Court denied them on Dec. 18, 2012 (Doc. 70). After that ruling, in January 2013, Relator provided a proposed protective order and a proposed amended Case Management Order to Defendants, along with initial discovery. An amended Case Management Order was entered on February 26, 2013 (Doc. 84), and initial document production commenced on April 25, 2013 pursuant to an interim confidentiality agreement entered into among the parties while the protective order issue was pending.

Under Rule 26(c), Fed. R. Civ. P., "[w]hile District Courts have the discretion to issue protective orders, that discretion is limited by the careful dictates of Fed. R. Civ. P. 26 and 'circumscribed by a long-established legal tradition' which values public access to court proceedings." *Procter & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219, 227 (6th Cir. 1996), *quoting Brown & Williamson Tobacco Corp. v. FTC*, 710 F.2d 1165, 1177 (6th Cir. 1983, cert denied, 465 U.S. 1100 (1984). "Rule 26(c) allows the sealing of court papers only 'for good cause shown' to the court that the particular documents justify court-imposed secrecy." *Id.* The burden is on the resisting party to show good cause for the protective.

Nix v. Sword, 11 Fed. Appx. 498, 500 (6th Cir. 2001); Crane Plastics, Co. v. Louisiana Pacific Corp., 119 F. Supp. 2d 749 (S.D. Ohio 2000) (J. Kemp). "To show good cause, [the resisting party] must articulate specific facts showing 'clearly defined and serious injury' resulting from the discovery sought and cannot rely on mere conclusory statements." Nix v. Sword, supra.

Defendants have a higher burden when it comes to "Attorneys Eyes Only" ("AEO") designations. An AEO designation is "the most restrictive possible protective order..." *Penn, LLC v. Prosper Bus. Dev. Corp.*, 2012 U.S. Dist. LEXIS 168577, *12 (S.D. Ohio Nov. 28, 2012) (J. Frost) (granting challenge to AEO designations). "A party seeking this designation must describe the alleged harm it will suffer from any disclosure 'with a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements." *Id. quoting Waite, Schneider, Bayless & Chesley Co., LPA v. Davis*, 2012 U.S. Dist. LEXIS 117634, at *14 (S.D. Ohio Aug. 21, 2012) (J. Kemp). "In the

² Quoting Nemir v. Mitsubishi Motors Corp., 381 F.3d 540, 550 (6th Cir. 2004). In Waite, the court made an AEO designation available for a specific settlement document sought in the case based on the affidavit from counsel that the confidentiality provisions of the agreement in question merited the extra layer of protection. 2012 U.S. Dist. LEXIS 117634 at *16-17.

business context, such a showing requires specific demonstrations of fact, supported where possible by affidavits and concrete examples." *Id.* (citations omitted)

Defendants have made no particular nor specific demonstration of fact to justify the most restrictive version of a protective order, much less submitted concrete examples of how it may be harmed or how that harm outweighs prejudice to the Relator.

Relator's proposed protective order, attached as Exhibit A, properly accommodates concerns over confidential, HIPAA-protected,³ and otherwise sensitive documents, and is in a form that has been recently endorsed by this Court in other gui tam cases.⁴

Conversely, Defendants' AEO proposal contains additional restrictions which are not called for by the HIPAA privacy rules and which are tied to amorphous category of "competitive" information from which Relator would be completely restricted from access. A comparison of this proposed category with the "Confidential Material" category demonstrates little difference between what Defendants propose to mark Confidential and what they want to mark "Attorneys' Eyes Only":

Defendants' Attorneys' Eyes Only Provision

- (1) Trade secrets;
- (2) Other sensitive confidential business or financial information and records, including strategic business planning or sensitive marketing information and the identity of suppliers, distributors and potential or actual customers, payer contracts or documents with payers that disclose terms, pricing, or strategic business alliances:

³ The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") governs the use and dissemination of personal health information. Under HIPAA and its implementing regulations, confidential health information can be used and disclosed in litigation pursuant to a qualified protective order. 41 C.F.R. § 164.512(e)(1). Relator's proposed protective order is a qualified protective order under HIPAA.

⁴ See United States ex rel. Meyer v. Kempf Surgical Appliances, Inc., No. 1:11-CV-0111 (Doc. 25) (S.D. Ohio, Western Div.) (J. Spiegel); United States ex rel. McDonough v. Symphony Diagnostic Services, Inc., et al., No. 2:08-cv-00114 (Doc. 57) (S.D. Ohio, Eastern Div.) (J. Marbley).

- (3) Competitive technical information, including technical analyses or comparisons of competitor's products or services;
- (4) Competitive business information, including non-public financial or marketing analyses or comparisons of competitors' products or services and strategic planning;
- (5) "Confidential Health Information." "Confidential Health Information" shall mean any document or information supplied in any form, or any portion thereof, that identifies an individual or subscriber in any manner and relates to the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual.
- (6) Any other material the disclosure of which to non-qualified people subject to this Protective Order the Producing Person reasonably and in good faith believes would likely cause harm.⁵

Definition of Confidential Material which is non-Attorneys' Eyes Only:

Produced Material which the parties reasonably believe in good faith constitutes confidential or proprietary technical, scientific, financial, business, competitive, health, medical, or other confidential or proprietary information designated as such by the producing party under Rule 26(c)(1)(G), Fed. R. Civ. P.⁶

Indeed, Defendants' proposed provision is so broad that it gives them the unfettered right to mark as AEO "[a]ny other material" they believe "would likely cause harm."

Defendants have not made the specific demonstration of fact necessary to support this restriction. First, they have not demonstrated what harm they will suffer from disclosure of information under the existing terms of the protective order. The provisions to which the parties have agreed, and which have been entered time and again in qui tam litigation in this district and others, restricts Rule 26(c) material from dissemination and specifically limits its use to "the prosecution or defense of the claims in this action." Ex. A at ¶ 7. The parties have already agreed that Confidential Information "shall not be used for

⁵ Defendants' Proposed Order, Attorneys' Eyes Only Category, Paragraph ¶ 1, p.2.

⁶ Parties' agreed provision, Ex. A at ¶ 1, p.1.

Page 5

any other purpose, including without limitation any business, commercial, competitive, or personal purpose, and shall not be disclosed except as provided in this Protective Order."

Id. Defendants have certainly offered no showing that Relator is likely to violate the terms of the Court's Order.

Second, Defendants have not demonstrated that Relator's access to documents poses any competitive harm. At the outset, it bears mentioning that Bostwick Laboratories is a national multi-specialty anatomic and clinical pathology laboratory with services in urology, gastroenterology, gynecology, nephrology and hematology, with seven divisions and more than 100 sales representatives. LabMD is a regional urology laboratory, currently servicing the southeastern U.S. with one sales representative. More to the point, however, Defendants have not identified anything about Relator's status as a regional laboratory owner that supports Bostwick's broad restrictive provision. The parties have agreed that the use of such information will already be governed by a protective order. Even if Relator were to violate the protective order – an inappropriate assumption —there is no showing that any particular discovery document could be used to Defendants' detriment.

Third, Defendants have not identified any of its competitive practices that they believe could be harmed by any specific document. Nor could they: Relator is seeking discovery about the illegal kickback schemes of Defendants – there is no argument that any individual could properly use such information to solicit referral sources in a similar

⁷ As reported in its 2008 SEC Filings (S-1 filed on 03/07/08) and on its website. http://www.bostwicklaboratories.com/Company/Divisions.aspx.

⁸ Relator's current territory includes Louisiana, Mississippi, Alabama, Florida, and Georgia. In previous years (from approximately 2004 through 2008), LabMD employed sales representatives in other states throughout the country, and still has long-time customers from that time frame in various other states.

manner. Not only would it violate the terms of the protective order, it would violate federal felony proscriptions. Moreover, the method by which Defendants were soliciting their customers is no secret – it is well laid out by the Amended Complaint. Not even the identity of Bostwick's competitive audience is a secret – certainly every laboratory knows the physicians and physician practices within its market. Defendants have not even identified (nor is Relator aware of) any current shared customers. Despite Relator's repeated request, Defendant has not identified any specific document as an exemplar of what might merit such restrictive protection.

Defendants have certainly made no showing to support such a restrictive provision in regard to patient records. There is no rational connection between Relator's status as a laboratory owner and Defendants' proposed provision to prevent him from access to records with patient-identifiers. Certainly, such information is routinely accessible by all parties in False Claims Act cases under a standard HIPAA-qualified Protective Order such as the one proposed by Relator (and previously entered in this district). 4 "Attorneys' Eyes Only" provisions are not required by HIPAA.

Finally, Defendants have made no showing that overcomes the harm to Relator from being prohibited access to the materials produced in this litigation. The broad designation proposed by Defendants would effectively prevent counsel from sharing substantive information regarding this litigation with their client, and prevent Relator from assisting counsel in assessing the records produced, along with anything else in the litigation which may rely on the use of such material, such as depositions and the

⁹ A qualified protective order under HIPAA is one that, by order or stipulation of the parties, "(A) [p]rohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and (B) [r]equires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding." 42 C.F.R. § 164.512(e)(1)(v).

engagement of consultants or expert witnesses. Relator is an industry insider, and it is untenable that counsel would not be able to work with their client in reviewing documents.¹⁰ Indeed, under Defendants' proposal, counsel would have to create two document databases just to share documents with their client (one containing "Confidential-only Material and one containing "Attorneys' Eyes Only" Material).

Relator should not be put in a position where he is "essentially kept in the dark about important facts of the case." *Arvco Container Corp. v. Weyerhaeuser Co.*, 2009 U.S. Dist. LEXIS 9264 *15 (W.D. Mich. Feb. 9, 2009) (internal citation omitted). As the *Arvco* court recognized, the "indiscriminate use of [AEO] protective orders does pose a significant handicap on the restricted litigant," making it "more difficult and expensive" if an attorney cannot make complete disclosure to the litigant and making it "difficult, and perhaps impossible" to counsel a client about compromise. 2012 U.S. Dist LEXIS 117634 at *15-16 *quoted in Waite*, 2012 U.S. DIst.. LEXIS 117634 at *15.

This result is prejudicial to Relator's ability to prosecute the case. Defendants have made no showing that of a "clearly defined and serious injury" which would justify this "extraordinarily confidential treatment." *Id.* Certainly, Defendants have made no showing that Relator would violate the existing confidentiality provisions in the agreed terms of the attached order.¹¹

Relator respectfully requests that the Court approve and enter the proposed protective order in the form attached hereto as Exhibit A.

¹⁰ For example, if AEO documents were provided to an expert or consultant, Relator's counsel would be in the position of engaging a consultant with whom his client could not communicate or, worse yet, to engage a consultant to substitute for the insider view of their own client.

¹¹ Moreover, "[a] litigant's vague feeling of discomfort or its desire to hobble its opponent in litigation to not establish good cause" for issuance of an attorneys eyes only protective order. *Arvco* at *23.

Respectfully,

/s/ Jennifer M. Verkamp

cc: W. Jeffrey Sefton

Michael S. Gardener Matthew D. Levitt

Stephanie Giuliano Abhar

Hope S. Foster Christopher L. Muzzo Stephen A. Miller Calli J. Varner

MINTZ LEVIN

Matthew D. Levitt | 617 348 1646 | MDLevitt@Mintz.com

One Financial Center Boston, MA 02111 617-542-6000 617-542-2241 fax www.mintz.com

May 20, 2013

VIA EMAIL

Hon. Karen Litkovitz United States Magistrate Judge Potter Stewart U.S. Courthouse 100 East Fifth Street Cincinnati, OH 45202

Re: U.S. ex rel. Daugherty v. Bostwick Laboratories, et al,

Civ. No. 1:08-cv-00354-SAS-KLL

Magistrate Judge Litkovitz:

In accordance with your Honor's instructions during the May 9, 2013 conference with the Parties, ^{1/} Defendant Bostwick Laboratories ("Bostwick") submits this letter brief in further support of the need and appropriateness of a two-tiered protective order providing for an Attorneys' Eyes Only designation. Bostwick attaches for the Court's consideration, at Exhibits 1 through 15, sample documents containing the types of information that it seeks to designate as Attorneys' Eyes Only. We have shared these documents with Relator's counsel, and, on May 17, we had a meet-and-confer teleconference to discuss them.

Relator's counsel insists that none of these fifteen documents merit Attorneys' Eyes Only protection, notwithstanding the highly sensitive information each contains. Bostwick respectfully disagrees. As explained in Bostwick's May 8th letter brief, and during the May 9th conference, an Attorneys' Eyes Only designation is a necessary and appropriate protective device here, where serious and potentially irreparable harm could result from Bostwick's compelled disclosure of its highly confidential commercial information directly to Relator, the president of a competing laboratory, particularly when Relator fails to identify any manner in which an Attorneys' Eyes Only designation will prevent him from effectively and efficiently litigating this case.

Throughout this letter, reference is made to Relator, Michael Daugherty, and Defendants Bostwick Laboratories and Dr. David Bostwick, collectively as "the Parties."

May 20, 2013 Hon. Karen Litkovitz Page 2 of 8

Relator has repeatedly acknowledged that he offers the same or similar laboratory services to urology practices as Bostwick does.^{2/} Nevertheless, in both his written submission to the Court and in subsequent discussions between counsel, Relator has taken the position that disclosure of Bostwick's sensitive competitive information directly to Relator will not result in competitive harm to Bostwick for two principal reasons.

First, Relator suggests that his status as a "regional urology laboratory" makes him incapable of causing competitive harm to Bostwick, a "national multi-specialty anatomic laboratory." Even if the Court were to accept Relator's representations that he currently solicits business only in the southeastern United States, these representations only serve to underscore the Parties' competitive relationship. As Relator is aware, at least half of Bostwick's laboratory operations are located in the southeastern United States. Relator cannot reasonably deny that the Parties therefore compete for the same physicians' business in their efforts to service a finite number of samples. While Relator suggests that his laboratory is much smaller than, and not a significant competitor of, Bostwick, this argument proves too much. A "small" laboratory would have more to gain from obtaining Bostwick's sensitive competitive information than would another laboratory with assets, clients, and industry experience comparable to Bostwick—a fact that Relator fails to dispute credibly.

Second, Relator argues that having direct access to Bostwick's sensitive competitive information could not pose any competitive harm because Relator is seeking discovery only about Bostwick's "illegal kickback schemes." For example, Relator's counsel has suggested that pricing is not confidential because laboratories do not compete on price, apparently contending that price differentiation in and of itself is unlawful. As the argument goes, Relator has charged Bostwick with unlawful behavior, which Relator—assuming the conclusion—states would be unlawful for him to copy, and therefore Bostwick has no valid interest in protecting such information. This is sophistry.

See, e.g., Amended Complaint, ¶ 20; Relator's Letter Brief, at p. 5.

Relator's Letter Brief, at 5.

See Defendants' Joint Answer, ¶ 17 (explaining that Bostwick currently operates a clinical pathology laboratory in Virginia and anatomic pathology laboratories in Florida, New York and London).

Relator's Letter Brief, at 5.

May 20, 2013 Hon. Karen Litkovitz Page 3 of 8

It bears repeating that Relator's allegations that certain of Bostwick's business practices are unlawful are just that—allegations. Bostwick vigorously contests these allegations vigorously, and in the course of doing so seeks to protect its hard-won confidential commercial information from falling into the hands of an admitted competitor. As to Bostwick's pricing information, Relator's unsupportable assertion that laboratories do not compete on pricing is inconsistent with Relator's own position that disclosing Bostwick's pricing information to competitors would cause no harm. Relator has argued that the pricing information that Bostwick provides to practices does not warrant the heightened protection of an Attorneys' Eyes Only designation because practices freely disclose this information to competing laboratories *in order to obtain better pricing.* This demonstrates that, as in any industry, pricing is a critical factor in winning business in the laboratory industry and that Bostwick's interest in protecting its pricing information is both legitimate and reasonable.

In any case, Relator's argument again proves too much. If Relator is correct that pricing information is readily ascertainable to industry players, then Relator cannot claim that he will be harmed if he is not provided direct access to such information through discovery. On the other hand, if Relator, as an "industry insider," does not already have access to pricing information, that fact demonstrates the precise reason why this information merits Attorneys' Eyes Only protection.

The competitive harm that will result to Bostwick, if forced to disclose sensitive competitive information such as pricing to Relator, is self-evident. The only adequate way to

And, of course, price competition is beneficial to payors, including Medicare and Medicaid, and is therefore encouraged. See, e.g., OIG Advisory Opinion No. 99-13 (noting that the discount safe harbor reflects Congressional intent to encourage price competition that benefits federal health care programs).

Relator's counsel has similarly suggested that more general information regarding Bostwick's customers also does not merit heightened protection because the identity and location of practices is common knowledge in the industry. While Bostwick does not seek to designate every document merely referencing a customer as Attorneys' Eyes Only, Bostwick's customer lists and similar documents compiling information regarding Bostwick's actual or prospective customers are entitled to this heightened protection. See, e.g., Asch/Grossbardt Inc. v. Asher Jewelry Co., 2003 U.S. Dist. LEXIS 2837, at *7 (S.D.N.Y. Feb. 28, 2003) (acknowledging that "[w]here the parties are direct competitors, as here, disclosure of customer lists could potentially result in economic harm to the disclosing party" and limiting access to defendant's customer list to plaintiff's counsel); Autotech Techs. L.P. v. Automationdirect.com, Inc., 235 F.R.D. 435, 446 (N.D. Ill. 2006) (explaining that "one of the most commonly used safeguards [to protect customer lists] is disclosure only to attorneys" and directing the parties to agree to a protective order to adequately safeguard the parties' interests).

Relator's Letter Brief, at 7.

May 20, 2013 Hon. Karen Litkovitz Page 4 of 8

protect Bostwick from such harm is through the entry of a protective order containing an Attorneys' Eyes Only provision.

To assist your Honor in evaluating Bostwick's request, we attach the following documents, all of which are responsive to Relator's discovery requests, as representative of the types of information that Bostwick seeks to protect through an Attorneys' Eyes Only designation.

Documents Revealing Specific Pricing Offered to Actual or Prospective Customers

Exhibit 1 sets forth the specific pricing Bostwick offered to a customer for the technical component of five laboratory tests. Disclosing this document to Relator would be competitively harmful because, with knowledge of Bostwick's exact pricing offer, Relator could offer more favorable pricing to this customer or similar customers to gain their business.^{9/}

Exhibit 2 is a contract for services between Bostwick and a customer located in Georgia, which Relator admits is a part of his "current territory." The first eight pages of this document set forth the general terms of the parties' agreement, and Bostwick does not seek to designate this portion of the document as Attorneys' Eyes Only. Exhibit B to the contract (*see* pages 9-18) discloses the exact prices at which Bostwick has agreed to provide its services to the practice, and therefore, Bostwick submits, merits heightened protection. With this pricing information, Relator could offer this or similar customers more favorable pricing for the same laboratory services.

Exhibit 3 is a Direct Bill proposal to a urology practice located in Georgia, where Relator admits he currently actively competes with Bostwick. As with Exhibits 1 and 2, the document sets forth the specific pricing offered by Bostwick to the prospective customer, which information Relator could use to undercut Bostwick.

Exhibit 4 is a proposal from Bostwick to a client to help establish an in-office laboratory. Bostwick seeks to designate as Attorneys' Eyes Only the proposed agreement itself, which contains the pricing at which Bostwick would provide these services to the client (*see* pages 7-

As much of the information that Bostwick would seek to designate as Attorneys' Eyes Only falls into this category of pricing information, we have included several examples of such information.

See Relator's Letter Brief, at 5.

^{11/} See id.

May 20, 2013 Hon. Karen Litkovitz Page 5 of 8

9). Relator could use this pricing information to offer to provide similar or, in light of the detail provided on the pricing list, identical services at prices lower than those Bostwick is offering.

Exhibit 5 is a Direct Bill agreement between Bostwick and a Florida customer, also in Relator's admitted territory. ^{12/} The agreement sets forth the negotiated pricing that Bostwick agreed to provide the customer and, as with Exhibit 2, could be used by Relator to offer more favorable pricing.

Exhibits 6 and 7 are internal emails attaching client price change forms. The price change forms disclose the negotiated prices that Bostwick has offered these clients for various laboratory procedures. Relator could use this information to undercut Bostwick, either with respect to these specific clients, or generally in the market.

Exhibit 8 is an internal email attaching a contract for services between Bostwick and a specific customer, which includes a test menu and schedule of list prices for Bostwick's American International Pathology Laboratories (AIPL) division (*see* pages 4-12). Relator could use knowledge of Bostwick's pricing to undercut Bostwick generally in the marketplace or with respect to this specific practice.

Exhibit 9 is an internal communication regarding Bostwick's pricing for various laboratory tests. Bostwick seeks to designate only the test menu and fee schedule attached to the cover email (beginning at page 5) as Attorneys' Eyes Only, as these documents disclose the negotiated pricing that Bostwick's sales representatives are authorized to offer prospective customers, without being required to consult their Regional Managers. Importantly, the test menu and fee schedule each have a different date than the same items that appear in the contract attached here as Exhibit 8. Relator could therefore use this information to determine how Bostwick's pricing has varied over time and to undercut Bostwick in the marketplace.

Documents Revealing Pricing Obtained from Suppliers and Partners

Exhibit 10 includes a spreadsheet documenting commissions earned by one of Bostwick's sales representatives, which provides extraordinarily detailed information on the specific tests ordered by individual physicians, and the amounts that Bostwick billed for those tests. As with Exhibits 1 through 9, discussed *supra*, Relator could utilize this information to undercut

May 20, 2013 Hon. Karen Litkovitz Page 6 of 8

Bostwick in the marketplace, generally, or specifically with respect to each identified customer. The spreadsheet also identifies the payor billed for each test. With knowledge of the exact amounts that each payor reimburses Bostwick for each test, Relator could negotiate more favorable fee schedules with private payors, to Bostwick's detriment.

Exhibit 11 contains a business strategy analysis prepared by Dr. David Bostwick regarding the possibility of Bostwick obtaining a new vendor for the supply of FISH probes. Bostwick does not seek to designate the cover email as Attorneys' Eyes Only, but would seek to designate the second two pages, which reveal the price that Bostwick pays for its probes, Bostwick's daily volume of FISH tests performed, and the reimbursement Bostwick receives for those tests. All of this information could be used by Relator to negotiate better pricing with its own vendors, or to capitalize on strategic business risks identified and evaluated by Bostwick.

Documents Revealing Market Strategy and Related Non-Public Information

Exhibit 12 is a document setting forth detailed business metrics regarding Bostwick's urology practice, including daily volumes of Bostwick's key products, actual and forecasted revenues, and details on Bostwick's recently-lost and recently-acquired business (*see* page 4). Information concerning the current status and health of Bostwick's business is of clear utility to a competitor like Relator, who could take advantage of such information in deciding how and when to launch sales campaigns in an effort to win business from Bostwick. The location information about where Bostwick derives its business is also of use to Relator in analyzing new areas to target, reconsidering his efforts in existing areas, or deciding how best to deploy his laboratory's resources in the marketplace. Finally, information regarding recently-lost and recently-gained business is useful to Relator insofar as it reveals which Bostwick clients do not have long-standing relationships and might therefore be considered "at risk" and likely worth seriously pursuing as a competitor.

Exhibit 13 are divisional team meeting minutes disclosing business metrics, including test volume. The document states, under the heading "lost business," "We were able to stop the loss of Dr. Joyce and Dr. Foad due to the lost specimen." This information reveals to Relator certain "at risk" customer relationships, which could then be used to entice clients to leave Bostwick and pursue services with another laboratory, like Relator's. The document also reveals identified

May 20, 2013 Hon. Karen Litkovitz Page 7 of 8

issues in Bostwick's turn-around-time (referred to in the document as "TAT"), which would provide Relator useful competitive information to attempt to differentiate his laboratory (i.e., he could represent to clients that his laboratory offers superior, and more consistent, turn-around-times).

Exhibit 14 is a communication from Bostwick's billing partner, McKesson, providing a detailed report of Bostwick's business metrics, including cash flow, cash projections, average reimbursements by payor (*see* page 12), and projected test volumes by procedure. As explained above, information on the health of Bostwick's business is valuable to a competitor like Relator, who can utilize such information in formulating and executing his own business strategy.

Documents Revealing Trade Secrets or Related Proprietary Information

Exhibit 15 is one example of Bostwick's standard operating procedures for its laboratory operations. Similar documents exist setting forth, step by step, the process by which Bostwick performs all laboratory operations, from sample accessioning through testing, and ultimately to quality control and reporting. This document sets forth the SOP for the performance and interpretation of UroVysion FISH testing. Among other things, it reveals when Bostwick will rely on automated screening versus requiring a manual screen (*see* page 1), as well as the number of screen captures that Bostwick requires to make a diagnosis (*see* page 3). Relator could use this information to revise or enhance his own laboratory processes.

Conclusion

The fifteen documents submitted with and discussed in this letter provide concrete examples of the types of competitive information that Bostwick sought to anticipate, in the abstract, in drafting its proposed protective order. If, after reviewing these sample documents, the Court is inclined to narrow that language, Bostwick would be happy to discuss ways of doing so during the informal hearing. Regardless of the final form of the order, however, Bostwick believes that these Exhibits demonstrate several categories of discoverable information—primarily pricing, but also internal business analysis and strategy—meriting Attorneys' Eyes Only protection under a two-tiered protective order. Bostwick therefore respectfully requests that the Court issue a protective order in a form similar to that it has proposed, permitting an Attorneys' Eyes Only designation for appropriate documents.

May 20, 2013 Hon. Karen Litkovitz Page 8 of 8

Respectfully submitted,

Muntin O. Luit

Matthew D. Levitt

cc: W.J. Sefton, Esq.
Hope S. Foster, Esq.
Michael S. Gardener, Esq.
Stefanie G. Abhar, Esq.

Christopher Muzzo, Esq. Stephen Miller, Esq. Calli Jo Varner, Esq.

Jennifer Verkamp, Esq. Frederick Morgan, Esq. James Keller, Esq.



MORGANVERKAMPLLC

By Electronic Mail

May 20, 2013

Hon. Karen Litkovitz United States District Court Judge for the Southern District of Ohio

Re: Letter Brief, U.S. ex rel. Daugherty v. Bostwick Laboratories, et al.,

Case No. 1:08-cv-354

Dear Magistrate Judge Litkovitz:

This letter follows up on the discussion of an "Attorneys Eyes Only" ("AEO") provision in the proposed protective order and, specifically, the production of a sampling of documents by Defendants which they would propose to mark AEO.

The idea of hiding discovery information from the person most able to assist counsel in assessing it is uniquely inappropriate in a case under the False Claims Act. Even if the information which the defendants are trying to hide from the Relator were sensitive and competitive—and Relator does not believe that it is—this is not a case brought for competitive advantage: The interest which has been damaged is that of the United States, and while it is important to attempt to level the competitive playing field by exposing and remedying competitive *disadvantages* caused by the use of kickbacks and overbilling of Medicare and Medicaid business, the fact that the Relator here also owns a medical testing laboratory is a benefit to the public interest, and that interest should not be hobbled because the defendant is worried, without basis, that Relator may violate the protective order. Congress certainly could have held that a competitor could not bring a *qui tam* case, but it imposed no such limitation on the universe of relators. Rather, the FCA specifically provides that "any person" can serve as a relator, including competitors. Indeed, the relator "stands in the shoes"

¹ U.S. ex rel. Walker v. R&F Prop. of Lake County, Inc., 433 F.3d 1349, 1359 (11th Cir. 2005) citing 31 U.S.C. § 3730(b).

Page 2

of the United States Government" to prosecute the lawsuit on its behalf. *Walker*, 433 FR.3d at 1355 (holding that the district court erred in limiting discovery to the term of relator's employment because claims belong to U.S. and the relator acts on its behalf). The statute is precisely designed for the relator to bring to bear his unique experience to detect and prosecute fraud against the United States. Though Defendants argue that the prejudice to relator is somehow slight because his lawyers can review documents, this is far from the case. Defendants' proposed provision would preclude or significantly obstruct relator from using his experience to assist litigating the case – creating a result directly contrary to the intent and purpose of the statute. To outweigh this significant prejudice (and the attendant costs of the litigation), Defendants must meet the burden of identifying the specific and actual competitive harm² which would result from confidential disclosure of documents under a protective order.

In follow up to the last conference, Defendant provided 15 examples of suggested AEO documents, regarding which the parties conferred on May 17, 2013. We believe that they fall into the following categories: (1) Pricing to customers; (2) Pricing from suppliers; (3) Market Analyses; (4) Revenue Analysis, and (5) Laboratory Policies and Procedures. We address each below.

Pricing of Laboratory Tests Provided to Customers: Docs. 0.7.2152093; DBL0000000003; 0009; 6600; 4539; 8543; 18099; 30823; 38625; and 41441. Defendants state that the overwhelming majority of documents for AEO are those containing pricing. Each of the documents in this category reflect pricing already disclosed to physician practices or hospitals (and notably, from some years ago). Such documents are not in fact confidential, in that they are provided to third parties and are routinely shared by those third parties with competitors. As put in *Arveo Container Corp.*, price is

² Defendants' burden is to show that "disclosure would cause significant harm to its competitive and financial position. That showing requires specific demonstrations of fact, supported where possible by affidavits and concrete examples, rather than broad, conclusory allegations of potential harm." *Arvco Container Corp. v. Weyerhaeuser Co.*, 2009 U.S. Dist. LEXIS 9264, *13-*14 (W.D. MI 2009) (citations omitted).

Page 3

not confidential in some markets because "the price level emerges from the interaction of demand with all firms' output decisions." 2009 U.S. Dist. LEXIS 9264 *19 (denying AEO protective order sought for pricing information).

In addition, in the regulated market of government healthcare providers, price is a much different issue than that between entities in the private marketplace. Claims to government healthcare programs are paid under the Medicare Fee Schedule, and are subject to set pricing. Providers that bill both public and private insurers are subject to the proscriptions of the Anti-Kickback Statute ("AKS") and cannot provide services to referral sources in exchange for less than fair market value, no matter the payor. The Compliance Guidance for Clinical Laboratories, issued by the Office of Inspector General ("OIG), summarizes this aptly:

Laboratories are paid for their services by a variety of payors in addition to Medicare and other Federal health care programs. Such payors often include private health insurers, other health care providers, and physicians. We believe it is essential that the physician take into account the patient's best interest when deciding where to refer the patient's specimen.

The prices that laboratories charge physicians for certain laboratory services raise issues that should be addressed in a laboratory's written compliance policies. These policies should ensure that laboratories are not providing any inducements to gain a physician's business, including charging physicians a price below fair market value for their non-Federal health care program tests. Laboratories that charge physicians a price below fair market value to induce them to refer their Federal health care program business may be risking anti-kickback enforcement and false claims actions.

63 Fed. Reg. 45076, 45081 (emphasis supplied). This is also laid out by the OIG's Special Fraud Alert for Clinical Laboratories:

Many physicians and other health care providers rely on the services of outside clinical laboratories to which they may refer high volumes of patient specimens every day. The quality, timeliness and cost of these services are of obvious concern to Medicare and Medicaid patients and to the programs that finance their health care services. Since the physician, not the patient, generally selects the clinical laboratory, it is essential that the physician's decision regarding where to refer specimens is based only on the best interests of the patient.

Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is

Page 4

offered to induce the referral of business. The same is true whenever a referral source solicits or receives anything of value from the laboratory. By "fair market value" we mean value for general commercial purposes. However, "fair market value" must reflect an arms length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them.

59 Fed. Reg. 65372, 65377 (December 21 1994) (emphasis supplied). In OIG Advisory Opinion No. 99-2, the OIG discusses illegal discounts which implicate the AKS, stating "we look for indicia that the discount is not commercially reasonable in the absence of other, non-discounted business." Discounts that are particularly suspect include, but are not limited to "discounted prices that are below the supplier's cost" and discounted prices that are lower than the prices that the supplier offers to a buyer that does not refer the same volume of business. OIG Adv. Op. 99-2 (referring in that case to the swap of discounts on purchased services for Part A inpatients, in exchange for the ability to bill Part B outpatient services).

Thus, pricing in the laboratory market is neither an unknown to any provider, nor a competitive differential for those who are complying with federal healthcare regulations.

While Relator does not contest Defendants' intention to mark such documents Confidential within the Protective Order, Relator asserts that these documents do not warrant AEO designation. Given the fact that Relator alleges that prices were offered below fair market value in exchange for the referral of government healthcare business, Relator will need to assess pricing information in order to prosecute that allegation. A provision prohibiting Relator from seeing such documents would prejudice Relator's ability to pursue that claim.

Of note, Relator's laboratory company does not or has not ever serviced hospitals, so such pricing cannot be asserted to work a competitive harm.

<u>Pricing From Suppliers:</u> Doc. DBL000006078. Defendants assert that pricing from suppliers warrant AEO designation, offering the above as an example. That document is an internal

Page 5

memorandum discussing the merits of switching suppliers for the equipment necessary to run the FISH test. Relator does not understand that there is any significant cost competition among laboratory suppliers, and it is unclear whether Defendants assert that there is. The particular memorandum provided does not demonstrate potential competitive harm as there are only two potential suppliers for the FISH equipment (known to the entire industry), and the identity of those suppliers is not confidential. While Relator does not object to this supplier analysis being marked Confidential, Relator does not agree that it warrants AEO designation. More importantly, Relator raised with Defendant's counsel that such analyses of suppliers is not specifically sought by Relator's discovery requests. Certainly, information about costs are relevant and discoverable to the extent they relate to fair market valuations, but detailed supplier evaluations do not, at this time, appear to be necessary.³

Market Analyses: Docs. DBL000006078, 6600. Defendants also assert that the document previously referenced in the supplier category, DBL000006078, should be designated AEO because it contains analysis by the company's executive committee of market strategies. Relator does not agree that this document is competitively harmful, because the identity of the suppliers are not confidential and the document discusses liability issues with breaking a contract with its supplier, which is Bostwick-specific. Another document reflecting marketing strategies employed by Defendants is DBL000006600, which reflects an arrangement involving the Tech 26 program and the setting up of an in-house laboratory in a physician practice. These strategies, among others, are identified in the Amended Complaint as violative of the AKS. Relator does not now, nor has ever, engaged in in-house laboratory management nor has offered what Bostwick calls in this document the "reverse Tech 26 business model." However, these strategies are obviously known to Relator

³Defendants assert that these documents were included in the production to the United States during the investigation of this case. Such documents were requested in Relators' discovery responses. Relator invited Defendants' counsel to confer on any categories of documents in that production which they believe to be inappropriate for re-production here.

Page 6

because they – among other kickback schemes – are the subject of the Amended Complaint. Relator cannot agree that documents discussing these strategies are competitively harmful.

<u>Financial Analyses</u>: DBL000029133, DBL000013362, DBL000017301. Defendants assert that documents with volume and revenue analysis are subject to AEO. While Relator agrees these can be properly marked Confidential under the Protective Order, it is difficult to ascertain how they may be used in a competitively harmful way. Defendants assert that knowledge of high-volume or high-revenue product lines may incentivize Relator to target that service (such as incentivizing the use of more FISH tests, presumably). However, because Relator alleges that many of Bostwick's revenues are generated by fraudulent practices, it is hard to discern how big picture numbers provide a competitive edge.

Of note, at DBL0000017301, there is a Lost Business analysis, which identifies the major competitors of Bostwick, which are not LabMD. Defendants assert this analysis would allow Relator to compete for the lost business. Defendants do not rebut Relator's counsel's understanding that the laboratories in each region well know who services each customer (and knows who the customers are). The information about the volume at each of those practices and the terms on which they would engage a laboratory to do business are not confidential, and are communicated freely to competing laboratories.

Lab Policies and Procedures: DBL000000596. Defendants state that their specific laboratory procedures merit AEO designation because their methods are premier laboratory methods and may be stolen and used by a competitor. However, the document provided sets forth procedures relating to the operation of the third party equipment used for FISH tests. The manufacturer sets the guidelines for use of this equipment. It is unclear how Defendants' procedures could substantively deviate with manufacturer's standards, particularly in a way as to operate a competitive harm. When

Page 7

Relator's counsel asked for a specific example of how a lab procedure (which are subject to CLIA inspection)⁴ could be competitively different, Defendants did not provide a concrete example.

Relator can see no basis for marking routine laboratory procedures under the most restrictive marking for a protective order.

In sum, Relator does not believe that the above examples support the addition of an AEO provision. Defendants concede they have no basis to believe that Relator would violate the terms of a protective order, and have provided no basis to include a virtually open-ended provision in the Protective Order. Defendants have provided no demonstration of current (not historical), internal (not communicated to third parties), proprietary business strategies (not the illegal schemes identified in the Amended Complaint) that could operate an actual competitive harm. Without that, there is no justification for the most restrictive protective order that outweighs the prejudice to Relator.

Respectfully,

/s/ Jennifer M. Verkamp

cc: W. Jeffrey Sefton
Michael S. Gardener
Matthew D. Levitt
Stephanie Giuliano Abhar
Hope S. Foster
Christopher L. Muzzo
Stephen A. Miller
Calli J. Varner

⁴ CLIA stands for the Clinical Laboratory Improvement Amendments which governs the quality standards applicable to laboratories. In general, laboratories must be CLIA-certified and are subject to inspection requirements.

MINTZ LEVIN

Matthew D. Levitt | 617 348 1646 | MDLevitt@Mintz.com

One Financial Center Boston, MA 02111 617-542-6000 617-542-2241 fax www.mintz.com

June 7, 2013

VIA EMAIL

Hon. Karen Litkovitz United States Magistrate Judge Potter Stewart U.S. Courthouse 100 East Fifth Street Cincinnati, OH 45202

Re: U.S. ex rel. Daugherty v. Bostwick Laboratories, et al,

Civ. No. 1:08-cv-00354-SAS-KLL

Magistrate Judge Litkovitz:

In accordance with your Honor's instructions during the May 22, 2013 discovery conference with the Parties, ^{1/} Defendant Bostwick Laboratories ("Bostwick") submits this letter brief in further support of the need for a two-tiered protective order providing for an Attorneys' Eyes Only designation. Bostwick also submits the affidavit of its Chief Compliance Officer, Gerard E. Diffley, which describes price competition among laboratories and the harm that would result if Relator, a competitor, were permitted direct access to Bostwick's proprietary pricing information. (*See* Exhibit A). In addition, Bostwick submits a corroborating affidavit from Kevin C. Johnson, a nonparty with extensive experience in the laboratory field. (*See* Exhibit B).

As Bostwick has argued in its previous letter briefs and during the discovery conferences on this issue, the Parties' relationship as competitors makes an Attorneys' Eyes Only designation appropriate and necessary for certain documents revealing Bostwick's proprietary information regarding pricing and costs.^{2/} Despite Relator's conflicting representations, there can be no

Throughout this letter, reference is made to Relator, Michael Daugherty, and Defendants Bostwick Laboratories and Dr. David Bostwick, collectively as "the Parties."

In light of your Honor's comments during the May 22 conference, Bostwick confines its arguments here to documents revealing (i) specific pricing offered to actual or prospective customers or (ii) pricing obtained from suppliers and partners. Bostwick maintains its position that an Attorneys' Eyes Only designation is warranted for the remaining categories of documents identified in its proposed protective order, submitted to the Court on May 8, 2013, and further illustrated by the exhibits submitted to the Court on May 20, 2013. As to those, Bostwick incorporates by reference the arguments advanced in its previous letter briefs.

June 7, 2013 Hon. Karen Litkovitz Page 2 of 6

dispute that Bostwick and Relator are direct competitors in the laboratory industry. Aside from a specific allegation to that effect in the Amended Complaint,^{3/} Relator publicly promotes himself—on his personal website—as the President and CEO of LabMD, which he describes as "an Atlanta-based clinical and anatomical medical laboratory with a <u>national client base</u>."^{4/} Accordingly, Relator's suggestion that LabMD does not or cannot compete with Bostwick due to LabMD's relative size and geographic scope is belied by Relator's own words.

There can therefore also be no dispute that disclosure of Bostwick's proprietary pricing information directly to Relator would result in immediate and possibly irreparable harm to Bostwick. Contrary to Relator's arguments, price competition among laboratories is no different from that in any other competitive market. Although laboratories compete based on a host of factors, pricing is among the most important factors in obtaining and maintaining business. Indeed, as detailed in the affidavit of Bostwick's Chief Compliance Officer, Gerard E. Diffley, who has over twenty-five years of experience in the laboratory industry, "doctors consider pricing to be one of the most important factors in purchasing laboratory testing." For this reason, Bostwick does not disclose the pricing it offers to one customer to its other customers. Nor does Bostwick share this information with its competitors.

As Mr. Diffley explains, with knowledge of the exact pricing that Bostwick offers to each customer, Relator could easily contact those customers and "undercut Bostwick's prices," causing Bostwick to lose those customers' accounts. The harm to Bostwick would not be limited to just those specific accounts, for Relator could easily use his acquired knowledge of Bostwick's pricing information to impair Bostwick's ability to compete with Relator elsewhere. With the advantage of knowing the specific pricing that Bostwick offers to certain customers, it would be relatively simple for Relator to determine the pricing that Bostwick would seek to charge similar prospective customers. Relator could then set out to undercut Bostwick

See Am. Compl., ¶ 20 ("In the course of his business, Relator provides similar laboratory services to physician customers, some of which have been or currently are also customers of Bostwick Laboratories.")

Diffley Affidavit, at ¶ 5, Ex. A (emphasis supplied).

^{5/} See id., at ¶ 2.

^{6/} *Id.*, at ¶ 6.

Id., at $\P 3$.

Id., at $\P 4$.

June 7, 2013 Hon. Karen Litkovitz Page 3 of 6

prospectively. This risk is even more acute where Relator seeks discovery regarding Bostwick's confidential financial information, such as detailed information regarding the current status and health of Bostwick's business. With knowledge of Bostwick's business limitations, Relator could offer pricing to practices that he knows Bostwick is unable to match, thereby threatening to force Bostwick out of a specific geographical market, such as Relator's "current territory." ^{9/ 10/}

The same is true with respect to the pricing that Bostwick has obtained from its business partners, including private payers. Just as Bostwick keeps confidential the pricing that it offers its customers, Bostwick also does not share with its competitors the pricing that it obtains from its various business partners. In fact, as Mr. Diffley explains, in many instances, Bostwick is contractually obligated to keep this information confidential.^{11/}

If Relator were to gain information regarding, for example, the reimbursement rates that Bostwick has obtained from a private insurer for a particular laboratory test, ^{12/} Relator could then use that information to propose to the insurer that his laboratory be added as an in-network provider at a lower reimbursement rate. As Mr. Diffley explains, this could result in harm to Bostwick in at least one of three ways. First, because private insurers are increasingly working to downsize their networks, Bostwick could be forced out of the insurer's network completely, in favor of Relator's laboratory. Second, and alternatively, Bostwick could be forced to accept the lower reimbursement rate that is now being offered to Relator, who has not negotiated such rate on fair footing. Third, even if the terms of Bostwick's own agreement are not affected, Bostwick would still be harmed because it would be forced to compete with Relator for in-network business that Relator likely could not have obtained but for learning the terms of Bostwick's confidential agreement. ^{13/}

See Diffley Affidavit, at ¶ 8.

Contrary to Relator's arguments, whether Relator has demonstrated any intent to misuse Bostwick's proprietary information is irrelevant. Simply put, once Relator obtains information regarding Bostwick's pricing, he cannot "unring the bell" and forget this information when actively competing with Bostwick in the market.

Id., at ¶ 9.

This very information is revealed in Exhibit 10, submitted by Bostwick to the Court on May 20, 2013.

Id. at ¶ 11.

June 7, 2013 Hon. Karen Litkovitz Page 4 of 6

The details set forth in Mr. Diffley's affidavit provide the precise type of information that Magistrate Judge Scoville found lacking in *Arvco Container Corp. v. Weyerhaeuser Co.*, 2009 U.S. Dist. LEXIS 9264 (W.D. Mich. Feb. 9, 2009), the case upon which Relator principally relies to argue that an Attorneys' Eyes Only designation is not appropriate to protect pricing information from direct disclosure to a competitor. In *Arvco*, Magistrate Judge Scoville did not hold that pricing information was not entitled to the heightened protections contemplated by Federal Rule of Civil Procedure 26(b)(1), but rather held that the defendant in that case had failed to make any showing that its pricing information was proprietary and therefore worthy of such protections. Instead, as the court pointed out, the defendant offered only "sketchy" and "vague" information regarding whether pricing was proprietary in that industry. ^{14/} By contrast, here, Mr. Diffley's affidavit states that (i) Bostwick considers the pricing that it offers specific customers to be confidential and does not share that information with other customers or with its competitors, and (ii) disclosure of Bostwick's pricing information to Relator, a direct competitor, would result in specific and identifiable harm to Bostwick. ^{15/} Mr. Johnson's affidavit similarly describes the confidentiality of pricing information in the laboratory industry. ^{16/}

Moreover, the facts and claims at issue in *Arvco* make the holding in that case inapposite to the issues presented here. Perhaps most importantly—and as Magistrate Judge Scoville pointed out twice in his decision—although the parties were competitors in the same industry, Arvco had brought its claims in its capacity as a customer of the defendant (Weyerhaeuser), not as its competitor. Indeed, Arvco's sole claim was that Weyerhaeuser had engaged in secondary-line price discrimination because it had refused to sell corrugated pizza boxes to Arvco at the same price offered to another customer, Star Pizza Box ("Star"). As a result of the nature of its claims, Arvco's discovery requests were limited to information regarding the pricing that Weyerhaeuser had offered to just one customer: Star.

By contrast, in this case, Relator has alleged that Bostwick is engaged in a "nationwide scheme" and, consequently, has requested discovery regarding virtually all of Bostwick's

See Arvco Container Corp., 2009 U.S. Dist. LEXIS 9264, at *21.

See Diffley Affidavit, at ¶¶ 2–8.

See Johnson Affidavit, at ¶¶ 4–5.

Arvco Container Corp., 2009 U.S. Dist. LEXIS 9264, at *6.

June 7, 2013 Hon. Karen Litkovitz Page 5 of 6

business practices over the past ten years. The potential harm to Bostwick, therefore, is much more significant and plausible than the harm that might have resulted from the disclosure of the defendant's pricing offered to just one customer in *Arvco*.

Finally, it bears noting that the *Arvco* defendant's highly obstructive conduct may have offered additional grounds for the court to deny the motion for a protective order limiting pricing information to the plaintiff's counsel and experts. Unlike here, the *Arvco* court had already entered one protective order governing discovery in that case. ^{18/} As Magistrate Judge Scoville noted, Weyerhaeuser had in fact agreed to the entry of the one-tiered protective order. Despite that order, Weyerhaeuser had unilaterally decided to withhold documents regarding the pricing it offered to Star on the basis that they were not relevant. ^{19/} In response to this behavior, the court stated that it was "distressed" with Weyerhaeuser's unilateral efforts to obstruct "discovery of the most basic conceivable information in a Robinson-Patman case" and warned that any "further obstruction" of discovery would be met with sanctions. ^{20/}

The same cannot be said here. Bostwick is diligently complying with its discovery obligations, having engaged in several meet-and-confer discovery conferences with Relator's counsel, and has worked with Relator's counsel to agree upon an interim confidentiality agreement subject to which Bostwick has produced more than 36,000 pages of responsive documents to date.

For these reasons and those previously articulated by Bostwick in its written and oral submissions, Bostwick respectfully requests that the Court issue a protective order permitting an Attorneys' Eyes Only designation for appropriate documents.

^{18/} Id. at *14.

^{19/} *Id.* at *8, 23.

^{20/} *Id.* at *24.

June 7, 2013 Hon. Karen Litkovitz Page 6 of 6

Respectfully submitted,

mantin N. durt

Matthew D. Levitt

cc: W.J. Sefton, Esq.
Hope S. Foster, Esq.
Michael S. Gardener, Esq.
Stefanie G. Abhar, Esq.

Christopher Muzzo, Esq. Stephen Miller, Esq. Calli Jo Varner, Esq.

Jennifer Verkamp, Esq. Frederick Morgan, Esq. James Keller, Esq.

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION AT CINCINNATI

UNITED STATES OF AMERICA ex rel.
MICHAEL DAUGHERTY

BRINGING THIS ACTION ON BEHALF
OF THE UNITED STATES OF AMERICA,
THE STATE OF TEXAS, THE STATE OF
GEORGIA, THE COMMONWEALTH OF
VIRGINIA, THE STATE OF TENNESSEE,
THE STATE OF NEW YORK, THE STATE
OF FLORIDA, THE DISTRICT OF COLUMBIA,
AND THE STATE OF INDIANA

Plaintiff and Relator,

٧.

BOSTWICK LABORATORIES

and

DAVID BOSTWICK

Defendants.

Case No. 1:08-cv-354

AFFIDAVIT OF GERARD E. DIFFLEY

- I, Gerard E. Diffley, do hereby state as follows:
- 1. I am the Chief Compliance Officer of Bostwick Laboratories ("Bostwick"), a position I have held since April 2012. Before joining Bostwick in April 2012, I worked for 22 years in various positions at Quest Diagnostics, a leading provider of clinical laboratory services, most recently as Corporate Director of Compliance and Patient Advocacy. I have held positions in sales, operations, and legal compliance. The information contained in this affidavit is based on

my combined twenty-five years of experience in the clinical laboratory industry, and my personal knowledge of the business practices of Bostwick and Quest Diagnostics.

- 2. The clinical laboratory industry is highly competitive. Laboratories such as Bostwick, Quest Diagnostics, and LabCorp compete vigorously for business, and there are a finite number of physicians and test samples they can service. Competition among clinical laboratories is based on a number of factors, with price being one of the most important. While Bostwick and other clinical laboratories attempt to differentiate themselves in other ways, such as laboratory turnaround time, pricing is among the most important issues in winning new business and maintaining existing business.
- 3. Like other clinical laboratories, Bostwick's pricing offered to particular practices is not simply "one size fits all." Rather, the prices charged to each practice for specific tests result from negotiations between Bostwick and the practice. Accordingly, Bostwick does not share the pricing offered to one customer with its other customers, and, for the same reasons, this information is not made available to the general public, including Bostwick's competitors.
- 4. If Bostwick's sensitive competitive information, including information regarding the pricing that it offers to specific practices, were to fall into the hands of a competitor, Bostwick's ability to effectively compete and succeed in the laboratory industry would be significantly impaired, in that it would be a simple matter for that competitor to call on Bostwick's existing customers and undercut Bostwick's prices. Even a small price difference (for example, \$1.00 per test) can have large impacts because of the thousands of tests a particular doctor will order each year. Therefore, even a small competitive advantage is likely to result in the loss of business to Bostwick.

- 5. One such competitor is LabMD, of which Relator, Michael Daugherty, is the founder and president. According to Relator's personal website (http://michaeljdaugherty.com), LabMD is "an Atlanta-based clinical and anatomic medical laboratory with a national client base." A copy of Relator's webpage, last accessed on May 31, 2013, is attached hereto as Exhibit A. Apart from LabMD's self-described national client base, I also understand from Relator's court submission in this case that LabMD currently competes with Bostwick for business in Georgia, Florida, Louisiana, Mississippi and Alabama.
- 6. As described above, if Relator were to gain information regarding the pricing that Bostwick offers to specific practices, especially those in LabMD's current service region, Relator could offer those practices lower prices for the same or similar services that Bostwick currently provides. My experience has been that doctors consider pricing to be one of the most important factor in purchasing laboratory testing. Because of this, Relator could capture Bostwick's current client base by offering even slightly lower pricing.
- 7. Bostwick's confidential pricing information is revealed in many of the documents responsive to the discovery requests served by Relator in this case. For example, of the exhibits submitted by Bostwick for review by the Court on May 20, 2013, Exhibits 1 through 5, and 8, each reveal the pricing that Bostwick offered to specific practices, many of which are located in LabMD's current service region. Exhibits 6 and 7 similarly reveal changes in the pricing that Bostwick offered to certain of its existing customers.
- 8. Relator's knowledge of Bostwick's pricing information could also severely impair Bostwick's ability to compete with Relator in Relator's current territory and in any territory in which Relator may enter in the future. Knowing Bostwick's pricing for certain customers, Relator could easily determine the pricing that Bostwick would seek to charge to similar

prospective customers, and then set out to undercut Bostwick prospectively. In addition, some responsive documents in this case, such as Exhibit 12 submitted by Bostwick on May 20, 2013, reveal Bostwick's confidential financial status, including its revenues and cash flows. With the advantage of knowing Bostwick's pricing and "bottom line," Relator could effectively force Bostwick out of a specific geographical market by offering pricing to practices that he knows Bostwick would be incapable of matching.

- 9. Just as Bostwick keeps confidential the pricing that it offers its customers, Bostwick also does not publicly disclose information regarding the pricing that Bostwick, as a customer, obtains from its business partners. In fact, Bostwick is obligated to keep this information confidential as a part of many of its contracts with its business partners.
- 10. A number of responsive documents in this case reveal the pricing that Bostwick has obtained from its business partners. For example, Exhibit 10, submitted by Bostwick on May 20, 2013, reveals the negotiated reimbursement rates that Bostwick has obtained from various private payors for specific laboratory tests. Exhibit 11 similarly reveals the discounted pricing that Bostwick has obtained from one of its suppliers, Abbott Laboratories, for fluorescent in situ hybridization (FISH) probes.
- able to negotiate more favorable pricing with his own business partners, or to obtain agreements with business partners that he might not have been able to obtain otherwise. This would work a competitive harm to Bostwick, in that Bostwick could lose its existing contracts, or be forced to accept less favorable terms from its business partners. By way of example, if Relator learned the reimbursement rates Bostwick has negotiated with a private insurer for a particular laboratory test (which is revealed in Exhibit 10), Relator could propose to that insurer that his laboratory be

Case: 1:08-cv-00354-SAS-KLL Doc #: 93 Filed: 06/26/13 Page: 54 of 73 PAGEID #: 1128

added as an in-network provider at a lower reimbursement rate. As it has been my experience

that private insurers are increasingly seeking to downsize their networks, this could cause

Bostwick to be forced out of the insurer's network entirely or to accept a lower reimbursement

rate to remain in-network. Even if Bostwick's own agreement is not affected, Bostwick would

still be harmed by virtue of having to compete with Relator for in-network business that Relator

could not have obtained but for learning the terms of Bostwick's confidential agreements.

I have personal knowledge of the facts stated herein and am willing to testify 12.

thereto.

Gerard E. Diffley

Chief Compliance Officer

Bostwick Laboratories

Dated: 07 June 2013

Exhibit A



MICHAEL J DAUGHERTY

LITTING OF THE INCOMING ROOK. THE DEVIL THE THE REI TWA



Home

Blog

Books 1

Visual Journal 1

/ledia

Cor

Contact

0







Home About - Michael J. Daugherty

About



Michael J Daugherty

Michael Daugherty is President & CEO of LabMD, an Atlanta-based clinical and anatomic medical laboratory with a national client base. LabMD specializes in analysis and diagnosis of blood, urine, and tissue specimens for cancers, micro-organisms and tumor markers. Mike founded LabMD in 1996 after 14 years in surgical device sales with U.S. Surgical Corp. and Mentor Corporation. Outside of LabMD, enjoys playing tennis, travel, and flying his Cirrus SR22 Turbo single engine aircraft. He is a member of the University of Michigan Alumni Association, the Atlanta Aero Club, and the Cirrus Owners and Pilots Association.Born and raised in Detroit, Michigan, Mike holds a BA in Economics from the University of Michigan-Ann Arbor, and has resided in Atlanta since 1987, when he moved to Atlanta from

Portland, Oregon.

Mike can be found on:

Facebook: http://www.facebook.com/daughertymichaelj

Twitter: https://twitter.com/daughertymj

Linkedin: http://www.linkedin.com/pub/michael-j-daugherty/19/8/7a5

Google+; https://plus.google.com/u/0/118277419398075017990/posts

Pinterest: http://pinterest.com/DaughertyMJ/

Subscribe!

Enter your email address to subscribe to my blog!

Email Address

Subscribe

Background — Four years ago, the US government teamed with a private enterprise to attack and take a file without authorization from an American small business. They used that information in order to expand and grow a government agency. What began with medical files taken without authorization from a laboratory, turned into a government supported extortion attempt.

Michael Daugherty, a small business owner who created LabMD, a cancer detection center in Atlanta, became a victim of a private cyber security company. That company, in association with a prestigious American university, conducted an invasion of business files and then used their findings to motivate the US Government to ride the wave of new cyber security protections and legislation.

Mr. Daugherty has engaged in an exhaustive effort to protect his company, one that saves lives, to repair his reputation and to ensure that this does not happen to any other American.

The book in engaging detail describes his experience of the last four years as he personally witnessed a government power grab and intimidation that if not for the fact that it is all real, would make for an a brilliant novel.

Google+

Share this:

Share

About



Michael Daugherty is President & CEO of LabMD, an Atlanta-based clinical and anatomic medical

laboratory with a national client base. Read more...

About: Wichael 9.03 Thickney | Milehael 9.40 ang Feilad: 06/26/13 Page: 58 of 73 PAGEID #gel31823

Designed by Bakerview Consulting | Powered by Wordpress

Home

Blog

Books

Visual Journal

Media

About

Contact











http://michaeljdaugherty.com/about/

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION AT CINCINNATI

UNITED STATES OF AMERICA ex rel.
MICHAEL DAUGHERTY

BRINGING THIS ACTION ON BEHALF
OF THE UNITED STATES OF AMERICA,
THE STATE OF TEXAS, THE STATE OF
GEORGIA, THE COMMONWEALTH OF
VIRGINIA, THE STATE OF TENNESSEE,
THE STATE OF NEW YORK, THE STATE
OF FLORIDA, THE DISTRICT OF COLUMBIA,
AND THE STATE OF INDIANA

Plaintiff and Relator,

٧.

BOSTWICK LABORATORIES

and

DAVID BOSTWICK

Defendants.

: Case No. 1:08-cv-354

AFFIDAVIT OF KEVIN C. JOHNSON

I, Kevin C. Johnson, do hereby state as follows:

1. I have more than 30 years of experience in the medical diagnostic laboratory industry. I currently serve on the board of directors of three laboratory and life science companies. From 1997 to 2003, I served as the Chief Executive Officer of Dianon Systems, Inc., a leading provider of pathology, genetic and clinical chemistry testing services. In 2003, Dianon Systems was acquired by LabCorp, which operates one of the largest clinical laboratory networks in the

world. Before joining Dianon Systems in 1996, I was employed for 18 years by Quest Diagnostics, another leading provider of clinical laboratory services, where I held various management and executive level positions. I have held positions in both sales and operations. The information contained in this affidavit is based on my experience in the medical laboratory industry, as well as my personal knowledge of the business practices of Dianon Systems and Quest Diagnostics.

- 2. Bostwick is a direct competitor of Dianon Systems and LabCorp, and during my tenure, Dianon actively competed for business with Bostwick. I am not now, nor have I ever been, employed by Bostwick Laboratories or Dr. David Bostwick. I have had no business relationship with either Bostwick or Dr. Bostwick, except for having performed, on behalf of a third party investment firm, due diligence on Bostwick Laboratories. I submit this affidavit freely, without any remuneration or expectation of such.
- It is my understanding that in this litigation certain questions have been raised regarding the nature of competition in the medical laboratory industry and whether laboratories regard their pricing information as proprietary.
- 4. In my experience, laboratories compete for business based on a number of factors, one of the most important of which is pricing. Because of this, laboratories such as Dianon and Quest consider the specific pricing that they offer to, for example, individual physicians, health plans and other non-government entities, to be confidential and do not disclose this information to other entities, or to competitors.
- 5. A laboratory with knowledge of the pricing that its competitor charges a particular physician has an advantage in the market, because it can offer that physician just slightly lower pricing and easily earn its business. For this reason, during my employment with Dianon and

Quest, those companies did not make their pricing available to the general public or to competitors such as Bostwick. If a competitor had learned of Quest's or Dianon's pricing and used that information, I expect that Quest or Dianon would have been harmed through a loss of business.

6. I have personal knowledge of the facts stated herein and am willing to testify thereto.

Kevin C. Johnson

Dated: JAN 7, 2013



MORGANVERKAMPLLC

By Electronic Mail

June 7, 2013

Hon. Karen Litkovitz United States District Court Judge for the Southern District of Ohio

Re:

Letter Brief, U.S. ex rel. Daugherty v. Bostwick Laboratories, et al.,

Case No. 1:08-cv-354

Dear Magistrate Litkovitz:

This letter follows up on the last conference with the Court regarding Defendants' proposed "Attorneys Eyes Only" ("AEO") provision, and specifically, the request for declarations regarding the competitive market. Attached at Exhibit 1 is the Declaration of Relator regarding the competitive market (discussed further below).

I. Standard of Review: Arvco v. Weyerhaeser.

Relator agrees with this Court's application of the standard set forth in *Arvco Container Corporation v. Weyerhaeuser Company*, that a party seeking AEO designation has the burden to show that "disclosure would cause significant harm to its competitive and financial position" and that the "party seeking such relief under Rule 26(c) must demonstrate the alleged harm 'with a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements." *Arvco*, 2009 U.S. Dist. LEXIS 9264 *16 (W.D. MI 2009). For the Court to impose what is the "most restrictive possible protective order," it "must be supported by a showing that disclosure will work a clearly defined and serious injury to the party seeking extraordinary confidential treatment." *Id*.

¹ See, Penn, LLC v. Prosper Bus. Dev. Corp., 2012 U.S. Dist. LEXIS 168577, *12 (S.D. Ohio Nov. 28, 2012) (J. Frost) (granting challenge to AEO designations).

II. The Competitive Market.

You have requested additional information regarding the nature and competitiveness of the laboratory services market, with a particular focus on the relevance of price.

A. Price is Only Offered in a Subset of Billing Scenarios.

Price is only relevant in a subset of situations in which laboratory services are billed. The laboratory services market is comprised of both government and private healthcare providers.

Claims to Medicare and other government healthcare programs are billed directly to the program under the Medicare Fee Schedule. That pricing is a set amount. In general, those claims are submitted directly to government healthcare programs by the provider who performed the service.

One exception to that general rule is where, as alleged here, a provider purchases some aspect of the test from the laboratory and then bills Medicare, such as by purchasing the technical component of the test. In that scenario, Bostwick provides the hospital or physician prices for the technical portion of the test. (Of note, Relator's laboratory, LabMD, does not provide any pricing for the technical portions of tests, nor does it service hospitals. Ex. 1, Dec. at ¶ 5, 7).

Claims to private payors are billed under amounts set by private insurance companies. Those claims may be submitted by the laboratory, or may be submitted by the ordering provider, such as a hospital or a physician practice. When the ordering provider submits the claims to the private payor, the laboratory may bill the provider for the cost of the tests under a pricing arrangement, often called an "account billing" or "direct billing" arrangement. OIG Advisory Opinion 99-13 at 2 (December 7, 1999).

B. Price is Subject to the Restrictions of the AKS.

In states where account billing is permitted, the price is still heavily regulated.² The Anti-Kickback Statute ("AKS") prohibits an entity for offering anything of value to a referral source if even one purpose of it is to induce government healthcare business. 42 U.S.C. § 1320a-7b(b); Adv. Op. 99-13 at 2. In the laboratory market, this restricts the amount of discounts a laboratory can offer a referral source for that subset of business that may be "account billed." As the Compliance Guidance for Clinical Laboratories spells out, laboratories should ensure that they "are not providing any inducements to gain a physician's business, including charging physicians a price below fair market value for their non-Federal health care program tests." 63 Fed. Reg. 45076, 45081. As concluded by OIG Advisory Opinion 99-13, "a discount arrangement between [a laboratory] and physicians utilizing account billing … may involve illegal remuneration to the physicians for their referrals of Federal health care program business not covered by the account billing arrangement and not subject to the discount."

In evaluating whether an improper relationship exists between a discount and referrals of Federal healthcare business, the OIG looks for "indicia that the discount is not commercially reasonable in the absence of other, non-discounted business." OIG Advisory Opinion 99-2. Discounts found to be particularly suspect include, but are not limited to, those which are below a the laboratory's costs and discounted prices that are lower than the laboratory offers to a buyer that does not refer Federal Healthcare business. OIG Adv. Op. 99-13; see also Adv. Op. 99-2.

Thus, this is not a market where providers can compete on price by offering, like a grocery store or Target, loss leaders on different products to entice the sale of other products. Rather, for the subset of services for which a laboratory can even offer a price (rather than bill the payor directly),

² In some states, account billing is illegal, based on the recognition, consistent with the AKS, that these arrangements can be conducive to fee-splitting.

the price must be reflective of market value and cannot be steeply discounted. Within the context of legal arrangements, there is not and cannot be a wide vacillation on price.

C. Price is Not Confidential.

Against this background is the fact that pricing information is freely shared. We agree that the *Arvco* court correctly captures that "[a]lthough price information can be proprietary, it may not be confidential in the least, depending on the circumstances." *Arvco*, *supra* at *19. In some circumstances, "there are no secrets about price, as buyers and sellers are fully informed about the price and availability of products." *Id*.

As Mr. Daugherty explains in the attached declaration (Ex. 1), the identity of customers and the prices they pay are not confidential. Ex. 1, Dec. at ¶ 10. Physicians and physician practices looking for discounted pricing routinely will share pricing information with competitor laboratories.³ Ex. 1, Dec. at ¶ 10- 11. To illustrate that fact, Exhibits A, B, and C to Mr. Daugherty's Declaration are Bostwick Laboratory pricing proposals provided to Mr. Daugherty (or to a LabMD sales representative) by physician practices. These pricing proposals are similar to ones provided as part of Defendants' Letter Brief dated May 20, 2013. For example, Exhibit A, an undated "Bostwick Laboratories TC Split Model" provided to Topeka Urology Clinic, is similar to Bostwick Exhibit 1 (Bates No. 0.7.215.20293), "TC-Split Revenue Assessment." Exhibit B, a 2008 proposal to Urology Associates of Atlanta for a Business Pathology Model, Reverse TECH, and Lab Solutions Business Model is in a different format, but contains information similar to Bostwick Exhibits 3, 4 and 5 regarding Client Bill Agreements (Bates DBL00000000009 and DBL000004539) and In-Office Laboratory Agreements (Bates DBL0000006600). Exhibit C, a 2007 "Client Direct Bill Agreement"

³ Bostwick Labs has argued that they fact that referral sources may also solicit discounted pricing is evidence that pricing can be variable. However, the fact that other players in the market may offer or solicit discounts does not make it appropriate. Certainly, no kickback scheme could be profitable unless referral sources participated.

is similar to Bostwick Exhibit 3 (Bates No. DBL000000009), a 2009 "Client Direct Bill Proposal" and Bostwick Exhibit 5 (Bates DBL000004539), a 2009 "Client Direct Bill Agreement."

If pricing documents were marked AEO, Relator would be in the odd position of being able to get such documents from third parties, while being prevented from having access to them when they are produced from Defendants. Because Defendants have not identified any "significant harm" to its competitive and financial position or "clearly defined and serious injury" (*Arvco* at *16) resulting from the production of pricing shared with third parties in a price-regulated market, such documents do not warrant the entry of an AEO provision.

D. Relator's Business is Otherwise Not in the Same Market as Bostwick.

Bostwick has identified other categories which it asserts are competitively harmful, such as supplier pricing or rates negotiated with private payors. However, as reflected in Mr. Daugherty's declaration, there is no significant competition among vendors of laboratory supplies. Dec. at ¶ 13. The pricing obtained for a small volume laboratory like Mr. Daugherty's, and one of a much larger laboratory like Bostwick Laboratories, are not similar and cannot be used competitively. *Id.*Moreover, the identities of suppliers are not confidential. For example, there are only two suppliers for FISH ("Flourescence In Situ Hybridization"), both of which are known in industry. *Id.*

Additionally, there is no significant competition for the amounts paid by private payors to laboratories of the size of Mr. Daugherty's laboratory. Dec. at ¶ 14. The business volume of LabMD does not allow it to negotiate differential pricing with private payors. *Id.*

Mr. Daugherty's laboratory is simply not in the same competitive market as Bostwick Labs. E.g., Dec. at ¶¶ 13-14. LabMD is a regional urology laboratory with a single sales representative and 20 accounts which currently services the states of Georgia, Tennessee, Louisiana, Mississippi, Alabama, and Northwest Florida. Dec. at ¶¶ 3-5. LabMD has no current shared customers with

Bostwick. *Id.* at ¶ 6. LabMD does not service hospitals. *Id.* at ¶ 5. LabMD does not split the billing of tests (ie., has never offered any TC Split or Tech 26 pricing proposals. *Id.* at ¶¶ 7-9. LabMD's only potential competitive status is in its uropathology services offered to physician practices in the states of Georgia, Tennessee, Louisiana, Mississippi, Alabama, and Northwest Florida.

E. Other Proposed AEO Categories.

Similarly, Bostwick argues that Relator could gain competitive advantage from access to information regarding internal operating procedures. Yet, as reflected in Mr. Daugherty's declaration, a laboratory's Standard Operating Procedures do not have competitive value. Dec. at ¶¶ 15-17. Mr. Daugherty knows of no occasion when a customer has even requested information regarding the SOP's. *Id.* at Dec. at ¶ 16.

Bostwick also argues that there are internal financial and market analyses that could allow Relator to gain a competitive advantage. However, Bostwick has identified no specific injury that could result from the Relator's access to Bostwick Labs total volume and revenue analysis, particularly since Relator alleges that Bostwick's marketing schemes (including its TC Split, Tech 26, and Lab Management practices) are illegal and result in false claims. As Relator identified at the last conference, only current information specific to obtaining the business of a particular customer within Mr. Daugherty's competitive region could arguably be competitively sensitive, though Mr. Daugherty would have to violate a protective order to use it to pursue new business opportunities.

II. If an AEO Provision is Entered, It Should Be Narrowly Restricted to Current And Internal Information.

As discussed in Relator's letter briefs, we do not agree that an "Attorneys' Eyes Only" designation is warranted in this case. Defendants have identified no "clearly defined and serious

injury" that would result, and concede that there is no basis to believe that Relator will violate the terms of a protective order. Defendants have certainly identified no harm that outweighs the harm to Relator from being prevented access to information. As is the case with most qui tam relators, Mr. Daugherty brings to bear unique insider knowledge, including 17 years of laboratory experience (Dec. at ¶ 2). Relator's counsel will rely on Mr. Daugherty's assistance in reviewing records in this case, including records related to the offers and solicitations made to physician practices (as alleged in the Amended Complaint).

If, however, the Court believes that an AEO provision is appropriate, Relator requests that it be narrowly restricted to very specific categories of current information. In close consideration of the Court's comments in recent conferences, Relator proposes that any AEO provision be narrowed to the following categories:

- 1. Current pricing information (dated after January 1, 2012) for direct bill arrangements to physician practices in the states of Georgia, Tennessee, Louisiana, Mississippi, Alabama, and Northwest Florida;
- 2. Current internal market analysis (dated after January 1, 2012) of factors relating to the gain, retention, or loss of business of a specific physician practice in the states of Georgia, Tennessee, Louisiana, Mississippi, Alabama, and Northwest Florida;
- 3. Internal laboratory procedures that Defendants in good faith believe to be proprietary, with the exception of any process or procedure relating to how FISH data and reports are provided to physicians for TECH26 analysis [*as the latter relates to one of the specific allegations of the Amended Complaint];
- 4. Current information (dated after January 1, 2012) about turn-around times for laboratory procedures.

If an AEO provision is entered, Relator additionally requests that Defendants provide an index of the bates numbers of AEO documents so that they can be properly marked (and masked) in electronic databases to which Relator will have access; and that, where feasible, a redacted version is provided so that the remainder of the document can be shown to Relator.

Respectfully,

/s/ Jennifer M. Verkamp

cc: W. Jeffrey Sefton

Michael S. Gardener Matthew D. Levitt

Stephanie Giuliano Abhar

Hope S. Foster

Christopher L. Muzzo Stephen A. Miller Calli J. Varner

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

United States of America ex rel. Michael Daugherty,

Case No.: 1:08 CV 354

Relator,

District Judge S. Arthur Spiegel

VS.

Magistrate Judge Karen L. Litkovitz

Bostwick Laboratories, et al.

Defendants.

DECLARATION OF MICHAEL DAUGHERTY

- 1. I am the Relator in the above-captioned action.
- 2. I have worked in the laboratory industry since 1996, and have owned a laboratory since 2000.
- 3. I am President of LabMD, a regional urology laboratory based in Atlanta, Georgia. We have one sales representative. Our entire market is comprised of Georgia, Tennessee, Louisiana, Mississippi, Alabama, and Northwest Florida.
- 4. From approximately 2004 through 2008, LabMD serviced other areas of the United States and continues to service a few long-time customers in those areas.
- 5. LabMD only provides services to approximately 20 physician practices, and has never serviced hospitals.
- 6. I am unaware of any current customers shared between Bostwick Laboratories and LabMD.
- 7. LabMD has never split the billing of tests with any provider. By this, I mean that LabMD has never billed only the Technical Component ("TC") of tests, and

has never offered what Bostwick calls the "reverse Tech 26 business model" in which Bostwick helps its provider clients bill the professional component ("PC") of tests.

- 8. LabMD has never provided in-house laboratory management services or helped practice groups set up their own laboratories.
- LabMD has never engaged in the practices identified in the Amended
 Complaint.
- 10. In my experience, competitors' prices are not confidential. Laboratory providers well know the identity of physician and physician practices in their respective regions. Those physician and physician practices readily disclose what laboratory services them, and the prices they pay.
- 11. Though not appropriate in the regulated government healthcare market, physicians and physician practices soliciting discounts routinely share the offers made by other laboratories. For example, attached as Exhibits A, B, and C are Bostwick Laboratory pricing proposals provided to me (or a LabMD sales representative) by physician practices.
- 12. Because of the restrictions on pricing arrangements under federal law, LabMD's business model does not involve undercutting competitors' pricing in order to gain business.
- 13. For laboratories of my size, there is no significant competition among vendors of laboratory supplies. The pricing obtained for a small volume laboratory like mine, and one of a much larger laboratory like Bostwick Laboratories, are not similar and cannot be used competitively. Moreover, the identity of suppliers are not

confidential. For example, there are only two suppliers for FISH ("Flourescence In Situ Hybridization"), both of which are known in industry.

- 14. For laboratories of my size, there is no significant competition for the amounts paid by private payors. The volume of my business does not allow me to negotiate differential pricing with private payors. I am not in the same market as that of a much larger laboratory as Bostwick.
- 15. I do not believe that a competitor's Standard Operating Procedures (SOP) relating to the operation of the laboratory and its equipment, including third-party equipment, have any competitive value. These procedures are technical and are subject to CLIA inspection. (CLIA refers to the Clinical Laboratory Improvement Amendments of 1998).
- 16. I have never had a physician or physician practice request information about my SOP's.
- 17. Equipment manufacturers set the guidelines for the use of their equipment, like the FISH test, and these should be reflected in the laboratories SOPs.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 7, 2013

lichael Daugherty